
**PREEMPTION & GENDER & RACIAL (IN)EQUITY:
WHY STATE TORT LAW IS NEEDED IN THE
COSMETIC CONTEXT**

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ABSTRACT

Much of the legal scholarship on the preemption of state tort law in the food and drug context and beyond has focused on issues of federalism. While the literature has considered the relationship between state tort law and the regulatory system, it has not generally explored the impact the federal preemption of state tort law may have on women and people of color. Similarly, while the literature has grappled with gender and racial justice issues in the tort system, including in the context of tort reform, it has largely not examined the gender and racial equity issues raised by federal preemption. This Article fills this gap by examining how the federal preemption of state tort law may perpetuate and even compound existing racial and gender inequities in the context of cosmetics. It considers how tort law, coupled with appropriate federal regulatory reform, may help lead to safer cosmetics for all.

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INTRODUCTION

The regulation of cosmetics is antiquated.¹ Over the past eighty-four years, the cosmetic provisions of the Federal Food, Drug, and Cosmetic Act (“FDCA”) have remained largely unchanged.² During that time, however, Congress has amended and strengthened the provisions for other products regulated by the Food and Drug Administration (“FDA”), including foods, drugs, and medical devices.³

Recent events involving cosmetics have highlighted limitations of the current regulatory framework for cosmetics.⁴ FDA’s authority with respect to cosmetics

¹ The Food and Drug Administration (“FDA”) Commissioner and the Director of the Center for Food Safety and Applied Nutrition (“CFSAN”) have referred to the regulatory framework as “outdated.” Press Release, U.S. FDA, FDA Statement: Statement from FDA Commissioner Scott Gottlieb, M.D., and Susan Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition, on Tests Confirming a 2017 Finding of Asbestos Contamination in Certain Cosmetic Products and New Steps that FDA Is Pursuing to Improve Cosmetics Safety (Mar. 5, 2019) [hereinafter Statement from FDA Commissioner], <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-susan-mayne-phd-director-center-food-safety-and> [https://perma.cc/76C4-NEZY]. Unlike foods, drugs, devices, biologics, veterinary products, and tobacco—which each have their own center at FDA—cosmetics are regulated by CFSAN. See *Center for Food Safety and Applied Nutrition (CFSAN)*, U.S. FDA (Sept. 19, 2018), <https://www.fda.gov/about-fda/office-foods-and-veterinary-medicine/center-food-safety-and-applied-nutrition-cfsan> [https://perma.cc/93VR-HQHE].

² Compare Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, §§ 601-604, 52 Stat. 1040, 1054-55 (1938) (originally codified at 21 U.S.C. §§ 361-364 (Supp. 4 1938)), with 21 U.S.C. §§ 361-363 (2018). In 1997, the Food and Drug Administration Modernization Act (“FDAMA”) added section 752, Preemption for Labeling or Packaging of Cosmetics, to the FDCA. See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, sec. 412, § 752, 111 Stat. 2296, 2376 (codified at 21 U.S.C. § 379s); see also *infra* Section I.E.2.

³ See, e.g., FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C.); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended in scattered sections of 21 U.S.C.); Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 21 U.S.C.); Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended in scattered sections of 21 U.S.C.); Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified as amended in scattered sections of 21 U.S.C.).

⁴ For example, on March 5, 2019, FDA warned consumers not to use certain cosmetics from Claire’s after FDA announced that samples of three products tested positive for asbestos. *FDA Advises Consumers to Stop Using Certain Cosmetic Products*, U.S. FDA (Aug. 24, 2020) [hereinafter *FDA Advises Consumers*], <https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-stop-using-certain-cosmetic-products> [https://perma.cc/8M7Z-BH4N]. In its alert, FDA noted that asbestos “is a known carcinogen” whose “health risks are well-documented.” *Id.* The FDA Commissioner and the Director of CFSAN in a joint statement stated that “FDA requested that Claire’s recall the products because they should not be used by consumers,” but that “Claire’s . . . refused to comply with the FDA’s request, and the agency does not have authority to mandate a recall.” Statement

is weaker than its authority with respect to the other major product categories.⁵ As a result, FDA cannot use many of the tools that it uses to regulate those other products to regulate cosmetics.⁶ For example, in contrast to—at least some—foods, drugs, and devices, there is no requirement that cosmetic establishments register with FDA;⁷ FDA is generally unable to inspect cosmetic records, including those related to safety;⁸ Good Manufacturing Practice (“GMP”) for

from FDA Commissioner, *supra* note 1. Less than a week later, the company announced a voluntary recall of the products. *Claire’s Stores, Inc., Announces Voluntary Recall of Three Make-Up Products*, U.S. FDA (Mar. 11, 2019), <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/claaires-stores-inc-announces-voluntary-recall-three-make-products> [<https://perma.cc/FTG5-BDFM>].

As another example, as of November 15, 2016, FDA had received 1,386 consumer reports about adverse reactions reported to be associated with WEN by Chaz Dean Cleansing Conditioners. *FDA Information for Consumers About WEN by Chaz Dean Cleansing Conditioners*, U.S. FDA (Nov. 3, 2017) [hereinafter *Information for Consumers About WEN*], <https://wayback.archive-it.org/7993/20171104085255/https://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm511631.htm>. In addition, “[w]hen the FDA inspected the manufacturing and distribution facilities for these products, [it] learned that consumers had reported reactions in more than 21,000 complaints submitted to . . . the companies that market and manufacture the products.” *Id.* Under current law, however, FDA does not have the authority to generally inspect cosmetic records, and companies are not required to report adverse events to FDA. FDCA § 704, 21 U.S.C. § 374; *see also Information for Consumers About WEN, supra*.

⁵ *See, e.g.,* Jordan Paradise & Ethan Fitzpatrick, *Synthetic Biology: Does Re-Writing Nature Require Re-Writing Regulation?*, 117 PENN ST. L. REV. 53, 70 (2012) (“Cosmetics are the least regulated product category that the FDA oversees.”).

⁶ *See* Marie Boyd, *Gender, Race & the Inadequate Regulation of Cosmetics*, 30 YALE J.L. & FEMINISM 275, 301-06 (2018).

⁷ *See id.* at 302. *Compare* FDCA § 510, 21 U.S.C. § 360 (requiring drug establishments to be registered with FDA), *id.* § 415, 21 U.S.C. § 350d (requiring food facilities to be registered with FDA), *id.* § 905, 21 U.S.C. § 387e (requiring tobacco establishments to register with FDA), 21 C.F.R. § 807.20 (2021) (requiring covered device establishments to be registered with FDA), *id.* ch. 1, subch. A, subpt. H (requiring food facilities to be registered with FDA), *and id.* pt. 207 (requiring “foreign and domestic establishment registration for human drugs, including drugs that are regulated under a biologics license application, and animal drugs”), *with id.* pt. 710 (detailing the “voluntary registration of cosmetic product establishments” with FDA), *and Voluntary Cosmetic Registration Program*, U.S. FDA (Aug. 24, 2020), <https://www.fda.gov/cosmetics/registrationprogram/default.htm> [<https://perma.cc/8QRD-UUQ2>] (stating that “[b]ecause product filings and establishment registrations are not mandatory, voluntary submissions provide FDA with the best estimate of information available about cosmetic products and ingredients . . . and businesses engaged in their manufacture and distribution”).

⁸ *See* FDCA § 704, 21 U.S.C. § 374; *id.* § 414(a)(1), 21 U.S.C. § 350c(a)(1); *see also* U.S. FDA, GUIDANCE FOR INDUSTRY: FDA RECORDS ACCESS AUTHORITY UNDER SECTIONS 414 AND 704 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (2014) [hereinafter FDA RECORDS ACCESS AUTHORITY], <https://www.fda.gov/media/83083/download> [<https://perma.cc/942S-2ZLJ>]; Statement from FDA Commissioner, *supra* note 1 (listing “access to records (including consumer complaints)” as a tool that “a more modern approach” to cosmetics regulation “could include”).

cosmetics is set forth in non-binding draft guidance and guidelines;⁹ manufacturers are not required to report adverse events for cosmetics;¹⁰ and cosmetics have no premarket approval requirements.¹¹ In addition, unlike for some establishments, the law does not establish the frequency of inspections of cosmetic establishments.¹² And FDA has no mandatory recall authority for cosmetics.¹³

In recent years, several unsuccessful bills have been introduced in Congress that would reform cosmetic regulation.¹⁴ The federal preemption of state law has emerged as a key issue in cosmetic reform, and cosmetics are poised to become

⁹ Compare 21 C.F.R. pts. 110-111 (providing current Good Manufacturing Practice (“cGMP”) for food and dietary supplements), and *id.* pts. 210-211, 225-226 (setting cGMP for drugs), and *id.* pt. 820 (establishing cGMP requirements for medical devices), with U.S. FDA, COSMETIC GOOD MANUFACTURING PRACTICES: DRAFT GUIDANCE 3 (2013) [hereinafter GOOD MANUFACTURING PRACTICES], <https://www.fda.gov/media/86366/download> [<https://perma.cc/L6QF-REQE>].

¹⁰ Compare FDCA § 761, 21 U.S.C. § 379aa-1 (requiring “[s]erious adverse event reporting for dietary supplements”), *id.* § 760, 21 U.S.C. § 379aa (requiring “[s]erious adverse event reporting for nonprescription drugs”), *id.* § 417, 21 U.S.C. § 350f(d) (reporting for reportable foods), 21 C.F.R. § 314.80 (describing reporting requirements for adverse events associated with drugs), and *id.* pt. 803 (describing reporting requirements for medical devices), with *Using Adverse Event Reports to Monitor Cosmetic Safety: A Conversation with Linda Katz*, U.S. FDA (Nov. 3, 2017) [hereinafter *Using Adverse Event Reports*], <https://www.fda.gov/cosmetics/complianceenforcement/adverseeventreporting/ucm531634.htm> [<https://perma.cc/3C7K-AA2T>] (indicating that among other limits to FDA oversight, FDA is not able to require “reporting of adverse events related to cosmetics”).

¹¹ *Cf.* FDCA § 409, 21 U.S.C. § 348 (setting forth requirements for approval of food additives); *id.* § 505(a), 21 U.S.C. § 355(a) (requiring premarket approval for new drugs); *id.* §§ 513(a)(1)(C), 515, 21 U.S.C. §§ 360c(a)(1)(C), 360e (requiring premarket approval for certain medical devices).

¹² See FDCA § 421, 21 U.S.C. § 350j; *id.* § 905(g), 21 U.S.C. § 387e(g); see also *id.* § 510(h)(2)(A), (3), 21 U.S.C. § 360(h)(2)(A), (3) (providing that device and drug establishments are to be inspected “in accordance with a risk-based schedule” established by the Secretary of Health and Human Services).

¹³ See *FDA Recall Policy for Cosmetics*, U.S. FDA (Aug. 24, 2020), <https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-recall-policy-cosmetics> [<https://perma.cc/9F4J-NPWY>] (explaining that the “FDA has no authority . . . to order a recall of a cosmetic”).

¹⁴ These bills include the Cosmetic Safety Enhancement Act of 2019, H.R. 5279, 116th Cong. (2019); the Safe Cosmetics and Personal Care Products Act of 2019, H.R. 4296, 116th Cong. (2019); the Personal Care Products Safety Act, S. 726, 116th Cong. (2019); the FDA Cosmetic Safety and Modernization Act, S. 2003, 115th Cong. (2017); and the Cosmetic Modernization Amendments of 2017, H.R. 575, 115th Cong. (2017). When this Article was written, one bill, the Personal Care Products Safety Act of 2021, was pending. S. 2100, 117th Cong. (2021).

the latest battleground over preemption in food and drug law.¹⁵ Preemption occurs when federal law displaces state or local law.¹⁶ Federal law can preempt state statutes or state tort law, for example.¹⁷ The Personal Care Products Council (“PCPC”)—“the leading national trade association representing cosmetics and personal care products companies”¹⁸—lists “National Program Uniformity”—i.e., preemption—as its first principle for federal cosmetic reform.¹⁹ Specifically, the PCPC states that it supports the

[p]reempt[ion of] state and local laws that would duplicate new authorities in the FDA regulation of cosmetics [and the] preempt[ion of] state and local laws for all cosmetic ingredients based on human health concerns if the FDA has reviewed the ingredient’s safety or has been presented with a safety review of the ingredient by the Expert Panel for Cosmetic Ingredient Safety and, after a period for the FDA review, has not rejected the Expert Panel’s safety finding.²⁰

Representative Frank Pallone, the Chair of the House Committee on Energy and Commerce, has stated in conjunction with cosmetic reform that preemption

¹⁵ See, e.g., *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019) (discussing federal preemption in context of prescription drug warnings); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 475-76 (2013) (discussing federal preemption in context of design defect claim); *Bruesewitz v. Wyeth, LLC*, 562 U.S. 223, 232 (2011) (discussing federal preemption in context of vaccine design defect claims); *Wyeth v. Levine*, 555 U.S. 555, 581 (2009) (discussing federal preemption in context of failure-to-warn claims); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008) (determining preemptive effect of the Medical Device Amendments of 1976); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 343-44 (2001) (discussing federal preemption in context of medical devices); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996) (determining preemptive effect of the Medical Device Amendments of 1976 on state negligence claim); *Hillsborough County v. Automated Med. Lab’ys, Inc.*, 471 U.S. 707, 723 (1985) (determining preemptive effect of federal regulation of plasmapheresis on county ordinances).

Despite the exclusion of cosmetics in its name, food and drug law includes cosmetics. See, e.g., FDCA §§ 601-603, 21 U.S.C. §§ 361-363; PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* chs. 1, 3 & 11 (4th ed. 2014).

¹⁶ *Preemption*, BLACK’S LAW DICTIONARY (11th ed. 2019).

¹⁷ See, e.g., Richard C. Ausness, *The Welding Fume Case and the Preemptive Effect of OSHA’s HazCom Standard on Common Law Failure-to-Warn Claims*, 54 BUFF. L. REV. 103, 109 (2006).

¹⁸ *About PCPC*, PERS. CARE PRODS. COUNCIL, <https://www.personalcarecouncil.org/about-us/> [https://perma.cc/7S6J-NL5U] (last visited Jan. 17, 2022).

¹⁹ *Legislative: PCPC’s Principles for Federal Cosmetics Reform*, PERS. CARE PRODS. COUNCIL, <https://www.personalcarecouncil.org/public-policy/federal-legislative-2021/> [https://perma.cc/7UC5-YBVF] (last visited Jan. 17, 2022).

²⁰ *Id.*

“is a major issue.”²¹ Whether the preemption of state tort laws specifically becomes a focus remains to be seen. However, there is some indication that it may as cosmetic manufacturers have raised preemption as a defense in lawsuits concerning cosmetic-talc products where plaintiffs have raised state tort law and other claims, albeit unsuccessfully.²²

This Article focuses on the potential impact of the federal preemption of state tort law on racial and gender equity in the cosmetic context. Specifically, it asks how the preemption of state tort law—and particularly products liability law—may “leave out or disadvantage women and members of other excluded groups.”²³ It argues that eliminating state tort law as a potential means of redress for people injured by cosmetics—people who may disproportionately be women

²¹ See Energy & Com. Comm., *Markup of 13 Health Bills*, HOUSE COMM. ON ENERGY & COM., at 47:24-47:26 (Mar. 11, 2020) [hereinafter *Markup of 13 Health Bills*], <https://energycommerce.house.gov/committee-activity/markups/markup-of-13-bills-subcommittee-on-health-march-11-2020> [<https://perma.cc/SA66-Y35B>]; see also *Hearing on “Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety” Before the Subcomm. on Health of the H. Comm. on Energy and Com. Comm.*, 116th Cong. 2 (2019) (statement of Rep. Frank Pallone, Jr., Chairman, Energy & Com. Comm.), https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/2019.12.4.PALLONE.%20FDA%20Cosmetics%20Leg%20Hearing.HE_.pdf [<https://perma.cc/REA6-JMCE>] (“I also understand that my colleagues and industry stakeholders still would like to see preemption language added to th[e] Cosmetic Safety Enhancement Act bill”); Ryan Nelson, *Cosmetic Safety Enhancement Act Advances in US House, Still Without Preemption*, HBW INSIGHT (Mar. 12, 2020) [hereinafter *Cosmetic Safety Enhancement Act Advances in US House*], <https://hbw.pharmaintelligence.informa.com/RS149785/Cosmetic-Safety-Enhancement-Act-Advances-In-US-House-Still-Without-Preemption> [<https://perma.cc/LU52-GDU2>]; Ryan Nelson, *US House Cosmetics Hearing: Preemption, FDA Ingredient Review Could Be Regulatory Reform Snags*, HBW INSIGHT (Dec. 5, 2019), <https://hbw.pharmaintelligence.informa.com/RS149491/US-House-Cosmetics-Hearing-Preemption-FDA-Ingredient-Review-Could-Be-Regulatory-Reform-Snags> [<https://perma.cc/96XL-HXUT>].

²² See *Feinberg v. Colgate-Palmolive Co.*, No. 50515(U), slip op. at 11 (N.Y. Sup. Ct. Mar. 22, 2012) (rejecting defendant’s express and implied preemption arguments); Order Denying Defendants’ Post Trial Motions, *Ingham v. Johnson & Johnson*, No. 1522-cc-10417, 2018 WL 7960293 (Mo. Cir. Ct. filed Dec. 19, 2018) (“This Court has previously considered Defendants’ preemption argument on this issue and found that Plaintiffs’ claims were not preempted.”); Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.’s Motion and Memorandum of Law in Support of Motion for Judgment Notwithstanding the Verdict at 36, *Ingham*, No. 1522-cc-10417, 2018 WL 7079682 (Mo. Cir. Ct. filed Sept. 20, 2018) (arguing that “Defendants are . . . entitled to judgment notwithstanding the verdict as to plaintiffs’ claims for failure to warn because they are preempted”); see also *Johnson & Johnson v. Fitch*, 2019-IA-00033-SCT (¶ 29), 315 So. 3d 1017, 1025 (Miss. 2021) (holding that “State’s claim is not barred by the principles of express or implied preemption” in a case brought by the Mississippi Attorney General under the Mississippi Consumer Protection Act); *infra* Section I.E.1.

²³ Katharine T. Bartlett, *Feminist Legal Methods*, 103 HARV. L. REV. 829, 831 (1990); see also Boyd, *supra* note 6, at 284-85 (asking an expanded version of the “woman question” about cosmetic law and regulation).

and members of other excluded groups—may make cosmetics less safe and exacerbate existing inequities.

Much is potentially at stake. A couple of examples illustrate the types of cases that preemption could impact and the potential scope of such cases. Johnson & Johnson indicated in a Security and Exchange Commission (“SEC”) filing that as of January 3, 2021, it was facing approximately 25,000 plaintiffs alleging direct claims in pending lawsuits regarding body powders—i.e., cosmetics—containing talc.²⁴ In one such lawsuit, *Ingham v. Johnson & Johnson*,²⁵ the plaintiffs obtained a \$4.69 billion jury verdict, which a court later reduced to \$2.2 billion.²⁶ The case involved women who claimed that the company’s products caused their ovarian cancer.²⁷ The plaintiffs alleged “claims for strict liability, negligence, and other torts.”²⁸ As another example, WEN by Chaz Dean, Inc. and Guthy-Renker, LLC settled—without admitting any wrongdoing—a class-action lawsuit that included state tort law claims for a little over \$26 million.²⁹ The plaintiffs alleged that the cosmetics—hair care

²⁴ Johnson & Johnson, Annual Report (Form 10-K), at 84-88 (Feb. 22, 2021). While the ultimate resolution of the talc cases remained to be seen, at the time that this Article was written, the company’s most recent 10-K indicated that in the cases that have gone to trial, “the Company . . . obtained defense verdicts in a number of them, but there have also been verdicts against the Company, many of which have been reversed on appeal.” *Id.* at 86. The company’s 10-K also indicates that “in certain circumstances the Company has . . . settle[d] cases.” *Id.* In its 2020 annual report, Colgate-Palmolive Company indicated that as of December 31, 2020, there were 137 individual cases pending against it, “alleging that certain talcum products that were sold prior to 1996 were contaminated with asbestos.” Colgate-Palmolive Co., Annual Report (Form 10-K), at 118 (Feb. 18, 2021).

²⁵ 608 S.W.3d 663 (Mo. Ct. App. 2020), *cert. denied*, 141 S. Ct. 2716 (2021).

²⁶ *Id.* at 680, 724; *J&J Loses Appeal of \$2.2 Billion Talc Verdict*, WASH. POST, Nov. 4, 2020, at A11 (reporting that the Missouri Supreme Court “refused to consider Johnson & Johnson’s appeal of a \$2.12 billion damages award to women who” filed suit claiming J&J’s baby powder and other talc products caused the women’s ovarian cancer); Amanda Bronstad, *As Mo. Supreme Court Lets Talc Verdict Stand, J&J Plans to Petition for SCOTUS to Review \$2.1B Award*, LAW.COM (Nov. 3, 2020, 5:07 PM), <https://www.law.com/2020/11/03/as-mo-supreme-court-lets-2-1b-talc-verdict-stand-jj-plans-to-petition-for-scotus-review-2-1b-talc-verdict/?sreturn=20210329115532>.

²⁷ *Ingham*, 608 S.W.3d at 678.

²⁸ *Id.*

²⁹ Order Granting Stipulation to File a Third Amended Complaint (152) and Granting Motion for Class Certification and Preliminary Approval of Class Settlement (153) at 1, 4-5, 18, *Friedman v. Guthy-Renker, LLC*, No. 2:14-cv-06009, 2016 WL 11756891 (C.D. Cal. Oct. 28, 2016) [hereinafter Order Granting Stipulation to File a Third Amended Complaint], ECF No. 178; *see also* Order Granting Final Approval of Settlement and Final Judgment at 2, *Friedman v. Guthy-Renker, LLC*, No. 2:14-cv-06009, 2017 WL 11646935 (C.D. Cal. Aug. 21, 2017), ECF No. 251; Julie A. Steinberg, *\$26M Chaz Wen Hair Product Deal Tentatively Approved*, BLOOMBERG L. (Nov. 1, 2016, 1:08 PM), https://www.bloomberglaw.com/bloomberglawnews/class-action/XFLMN1BO000000?bna_news_filter=class-action#jcite.

products—caused hair loss and scalp irritation.³⁰ If cosmetic tort law claims were preempted, plaintiffs would be unable to maintain such claims.

The question of whether federal law should preempt state tort law—and if so to what extent—has important equity implications as the risks that the failures in the regulation of cosmetics engender may disproportionately fall on women, particularly those who are members of other historically excluded groups.³¹ Cosmetic use and exposure may vary by gender, race, and socioeconomic status. For example, surveys have found that women, on average, use more cosmetics than men.³² Moreover, women are more likely than men to be employed in jobs that frequently involve exposure to cosmetics.³³

³⁰ See Order Granting Stipulation to File a Third Amended Complaint, *supra* note 29, at 2.

³¹ Boyd, *supra* note 6, at 289 (“[B]ecause cosmetics are a highly gendered product and industry, failures in cosmetics law and regulation may disproportionately jeopardize the health of women, particularly women who are members of other excluded groups.”). Others have noted that the effects of preemption may disproportionately impact certain demographic groups, including women in other contexts. See, e.g., Eric Lindenfeld, *The Unintended Pregnancy Crisis: A No-Fault Fix*, 17 MARQ. BENEFITS & SOC. WELFARE L. REV. 285, 306 (2016) (discussing preemption in context of contraceptive products and noting that “women . . . are now at an even greater risk of being barred from any form of compensation”); Courtney A. Markey, *Implications of the Supreme Court’s Decision in Pliva, Inc. v. Mensing: Why Generic and Brand-Name Pharmaceuticals Must Be Treated Equally Under the Federal Food, Drug, and Cosmetic Act*, 15 MARQ. ELDER’S ADVISOR 135, 159 (2013) (discussing the U.S. Supreme Court’s preemption holding in *PLIVA v. Mensing* [564 U.S. 604 (2011)] and arguing that “women, minorities, and the elderly” are “disproportionately harmed by [that] decision”); see also Thomas Koenig & Michael Rustad, *His and Her Tort Reform: Gender Injustice in Disguise*, 70 WASH. L. REV. 1, 46-55 (1995) (discussing efforts to “bar punitive damages in any case where a drug or medical device has received pre-market approval from FDA” and how this “FDA Defense” may impact the ability “for women to find redress for mass product liability injuries”).

³² See, e.g., *Discussion Draft of the Food and Drug Administration Globalization Act Legislation: Device and Cosmetic Safety Provisions: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Com.*, 110th Cong. 134, 141 (2008) (statement of Jane Houlihan, Vice-President for Research, Environmental Working Group); *Exposures Add Up – Survey Results*, ENV’T WORKING GRP. (2004) (archived at <https://perma.cc/VGC4-BZBX> on Nov. 3, 2018); *Survey*, YOUGov (Sept. 11, 2013), https://cdn.yougov.com/cumulus_uploads/document/ypg8eyjbsv/tabs_skincare_0910112013.pdf [<https://perma.cc/UR2N-ZRFA>]. Men’s attitudes, however, towards certain cosmetics may be changing. See, e.g., Joanna Piacenza, *As Beauty Norms Blur, One-Third of Young Men Say They’d Consider Wearing Cosmetics*, MORNING CONSULT (Oct. 28, 2019, 12:01 AM), <https://morningconsult.com/2019/10/28/as-beauty-norms-blur-one-third-of-young-men-say-theyd-consider-wearing-cosmetics/> [<https://perma.cc/LLM6-3679>] (stating that 33% of men ages eighteen to twenty-nine and 30% of men ages thirty to forty-four said “they would consider wearing makeup”).

³³ For example, in 2020, 93.9% of skincare specialists; 90.8% of hairdressers, hairstylists, and cosmetologists; and 79.3% of manicurists and pedicurists were women. *Labor Force Statistics from the Current Population Survey*, U.S. BUREAU OF LAB. STATS. tbl.11 (Jan. 22, 2021) [hereinafter *Labor Force Statistics*], <https://www.bls.gov/cps/cpsaat11.htm>

Studies have also found racial and ethnic differences in the purchase and use of certain cosmetics as well as “[t]argeted racial/ethnic marketing.”³⁴ These differences may lead to differences in potentially harmful chemical exposure, which may disproportionately impact “vulnerable and underserved women.”³⁵ For example, “[c]ompared with white women, women of color have higher levels of beauty product–related environmental chemicals in their bodies,” which may have negative health repercussions.³⁶

State tort law can help fill gaps in the federal regulation of cosmetics—including the gaps that would likely remain under the recent reform proposals.³⁷

[<https://perma.cc/8JD3-LHRG>]. These statistics, however, do not mean that men do not use cosmetics. They do. In fact, the men’s personal care industry is growing. *See, e.g.,* Nia Warfield, *Men Are a Multibillion Dollar Growth Opportunity for the Beauty Industry*, CNBC (May 20, 2019, 3:20 PM), <https://www.cnbc.com/2019/05/17/men-are-a-multibillion-dollar-growth-opportunity-for-the-beauty-industry.html> [<https://perma.cc/VJV2-PQNX>].

³⁴ *See* 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, 419 (2017) (discussing “disproportionate beauty product exposures among vulnerable populations” and citing various studies).

³⁵ Zota & Shamasunder, *supra* note 34, at 418.e1, 419 tbl.; Jessica S. Helm, Marcia Nishioka, Julia Green Brody, Ruthann A. Rudel & Robin E. Dodson, *Measurement of Endocrine Disrupting and Asthma-Associated Chemicals in Hair Products Used by Black Women*, 165 ENV’T RSCH. 448, 455 (2018) (“[A] wide range of endocrine disrupting and asthma-associated compounds [are] in hair products used by Black women, including products marketed towards children.”); *Big Market for Black Cosmetics, but Less Hazardous Choices Limited*, ENV’T WORKING GRP. (Dec. 6, 2016) [hereinafter *Big Market for Black Cosmetics*], <https://www.ewg.org/research/big-market-black-cosmetics-less-hazardous-choices-limited> [<https://perma.cc/48KX-F7QW>] (stating that “[a] smaller share of hair and beauty products marketed to Black women scored low in potentially harmful ingredients than products aimed at the general public” and that this “could mean they are being exposed to more potentially hazardous chemicals”); *see also* Patrick Celestine, *Righting the Imbalance in Toxic Cosmetics*, TRIAL, May 2020, at 52, 52 (arguing that “[l]egislation to regulate cosmetics and ban asbestos is needed to protect everyone who uses contaminated products, especially women of color, who are disproportionately affected by toxic cosmetics”).

³⁶ Zota & Shamasunder, *supra* note 34, at 418.e1; *see also* AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, NO. 832, REDUCING PRENATAL EXPOSURE TO TOXIC ENVIRONMENTAL AGENTS, in 138 OBSTETRICS & GYNECOLOGY e40, e47, e50 (2021), <https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2021/07/reducing-prenatal-exposure-to-toxic-environmental-agents.pdf> [<https://perma.cc/C34A-CXHL>] (discussing personal care products as a potential source of toxins); *id.* at e41 (stating that “effects of exposure to environmental chemicals can be exacerbated by injustice, poverty, neighborhood quality, housing quality, psychosocial stress, and nutritional status”); AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, NO. 575, COMPANION PIECE TO 575: EXPOSURE TO TOXIC ENVIRONMENTAL AGENTS (2013) (withdrawn) (archived at <https://perma.cc/4Z47-PEMN> on May 12, 2021) (“Although exposure to toxic environmental chemicals is universal, harmful environmental exposure is inequitably and unequally distributed, which leaves some populations, including underserved women, more vulnerable to adverse reproductive health effects than other populations.”).

³⁷ *See infra* Section I.D.

Despite its limitations,³⁸ state tort law can help to complement and strengthen the regulatory system, which confers no private right of action on consumers injured by cosmetics.³⁹ State tort law can provide recognition, redress, and compensation to consumers injured by cosmetics,⁴⁰ serve a deterrent function, encouraging manufacturers to take due care,⁴¹ and reveal important information about product risks and safety.⁴² Preempting cosmetic claims would eliminate these potential benefits.

This Article proceeds as follows: Part I defines cosmetics and provides an overview of the existing regulatory framework for cosmetics and its substantial limitations. It considers some of the potential risks of cosmetics and why they may disproportionately impact women, particularly women who are members of other historically excluded groups. It also considers the federal preemption of state tort law claims under current law. Part II argues that the federal preemption of cosmetic claims based on state tort law would be detrimental to consumer health and safety and would put consumers in an even worse position than they currently are. However, even if Congress enacts cosmetic reforms, preserving state tort law claims would be important for consumer health and safety. Part II also argues that the federal preemption of cosmetic claims based on state tort law would have a disparate impact on women, particularly women who are members of other excluded groups—groups for whom tort law may offer especially significant, yet flawed, benefits in light of other disparities, such as those in healthcare. Part III then builds on Part II by undertaking an examination of recent litigation involving cosmetic-talc products. This examination highlights the importance of state tort lawsuits in advancing gender and racial equity in the cosmetic context. While this Article focuses on why Congress should expressly preserve state tort law claims and why both state tort law and federal regulation are needed in the cosmetic context, this analysis has implications for the broader debate over the preemption of state tort law claims.

³⁸ For a discussion of the limitations of tort law, including how it may perpetuate existing gender and inequalities, see *infra* Section II.C.2.

³⁹ See Federal Food, Drug, and Cosmetic Act (FDCA) § 310, 21 U.S.C. § 337 (limiting proceedings to be brought by the United States, and in some instances, the states); see also James M. Beck & John A. Valentine, *Challenging the Viability of FDCA-Based Causes of Action in the Tort Context: The Orthopedic Bone Screw Experience*, 55 FOOD & DRUG L.J. 389, 402 (2000) (discussing the preclusion of private rights of action for FDCA violations).

⁴⁰ See, e.g., Robert L. Rabin, *Poking Holes in the Fabric of Tort: A Comment*, 56 DEPAUL L. REV. 293, 301 (2007) (discussing “the costs” of regulatory preemption and stating that “[m]ost obviously, victims are left without compensation when the defendant’s conduct conforms to regulatory standards but causes injury nonetheless”); see also 74 AM. JUR. 2D *Torts* § 2, Westlaw (database updated Nov. 2021) (“[A] principal function of tort law is to compensate a victim for wrongdoing or unreasonable conduct of the tortfeasor.”).

⁴¹ See, e.g., DAN B. DOBBS, PAUL T. HAYDEN & ELLEN M. BUBLICK, *HORNBOOK ON TORTS* § 2.5, at 23-24 (2d ed. 2016); Rabin, *supra* note 40, at 301.

⁴² See *infra* Section II.B.4.

I. COSMETIC SAFETY, FEDERAL REGULATION & PREEMPTION

A. *Definition*

This Article focuses on products that are solely “cosmetics.”⁴³ “Cosmetics” are “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance” or “articles intended for use as a component of any such articles.”⁴⁴ Cosmetics include makeup (e.g., “lipstick, blush, foundation, face powder, eye shadow[,], eye liner, and mascara”),⁴⁵ hair products (e.g., “[d]yes, relaxers, [and] removers”),⁴⁶ nail products, tattoos and permanent makeup, some cleansing products, and some lotions.⁴⁷

This Article excludes from consideration products that meet the definition of cosmetics *and* the definition of another FDA-regulated product category. Accordingly, this Article does not address products such as breast implants, Latisse, and Botox Cosmetic. FDA regulates these products not as cosmetics but as devices, drugs, and biologics, which are subject to more stringent regulation.⁴⁸

In addition, “color additives” are excluded from consideration here. Although “color additives” are often used in or as cosmetics, they are a distinct regulatory

⁴³ Federal Food, Drug, and Cosmetic Act (FDCA) § 201(i), 21 U.S.C. § 321(i) (defining “cosmetic”).

⁴⁴ *Id.* The definition of “cosmetic” excludes “soap,” which is defined narrowly based on its composition, the ingredients responsible for its cleaning action, and its intended use. *See* 21 C.F.R. § 701.20 (2021) (defining soap).

⁴⁵ *Makeup*, U.S. FDA (Aug. 24, 2020), <https://www.fda.gov/cosmetics/cosmetic-products/makeup> [<https://perma.cc/A9BA-CJPG>].

⁴⁶ *Cosmetic Products*, U.S. FDA (Aug. 24, 2020), <https://www.fda.gov/cosmetics/cosmetic-products-ingredients/cosmetic-products> [<https://perma.cc/NBH4-A9EF>].

⁴⁷ *Id.*; *Soaps & Lotions*, U.S. FDA (Aug. 24, 2020), <https://www.fda.gov/cosmetics/cosmetic-products/soaps-lotions> [<https://perma.cc/86C6-MHYP>] (“Lotions . . . and other cleansers may be regulated as cosmetics or as other product categories, depending on how they are intended to be used.”).

⁴⁸ *See* U.S. FDA, Ctr. for Drug Evaluation & Rsch., NDA 22-369, Approval Letter for Latisse (Dec. 24, 2008), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2008/022369s000_Approv.pdf [<https://perma.cc/AL9R-VG57>] (approving Latisse for the “treatment of hypotrichosis of the eyelashes by increasing their growth including length, thickness and darkness”); U.S. FDA, Ctr. for Drug Evaluation & Rsch., STN BL 103000/5000, Approval Letter for Botox Cosmetic (Apr. 12, 2002), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/botual1041202L.htm [<https://perma.cc/ZQ2L-6NR5>] (approving a biologic license supplement for Botulinum Toxin Type A for the “treatment of glabellar lines”); *Breast Implants*, U.S. FDA (Oct. 27, 2021), <https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants> [<https://perma.cc/EP3Q-MNFX>] (noting that breast implants are medical devices and that FDA has approved two types of breast implants for sale in the United States).

category subject to their own regulatory requirements.⁴⁹ The FDCA defines a “color additive,” in part, as a substance that “when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable . . . of imparting color thereto.”⁵⁰ Unlike cosmetics, FDA must approve (i.e., “list”) color additives before use.⁵¹ In addition, FDA may approve color additives for use in products other than cosmetics.⁵²

B. *Industry Overview*

Cosmetics are big business. According to IBISWorld, the total revenue for cosmetic and beauty products manufacturing in the United States in 2019 was estimated to be \$52.3 billion.⁵³ While the exact number of cosmetic manufacturers in the United States is unknown because they are not required to register with FDA,⁵⁴ IBISWorld estimated that 4,046 cosmetic and beauty products manufacturing enterprises were in the United States in 2019.⁵⁵ Similarly, the number of foreign companies that manufacture cosmetics for or export to the United States is unknown due to the lack of required reporting.⁵⁶ However, in 2017, FDA estimated that there were 29,000 such companies.⁵⁷

⁴⁹ See FDCA § 201(t)(1), 21 U.S.C. § 321(t)(1); *Color Additives Permitted for Use in Cosmetics*, U.S. FDA (Oct. 7, 2021), <https://www.fda.gov/cosmetics/cosmetic-ingredient-names/color-additives-permitted-use-cosmetics> [<https://perma.cc/WEC3-DK3L>].

⁵⁰ FDCA § 201(t)(1)(B), 21 U.S.C. § 321(t)(1)(B).

⁵¹ *Id.* § 721(a), (b)(1), 21 U.S.C. § 379e(a), (b)(1); *id.* § 402(c), 21 U.S.C. § 342(c); *id.* § 601(e), 21 U.S.C. § 361(e).

⁵² *Id.* § 721, 21 U.S.C. § 379e (setting forth requirements for “[l]isting and certification of color additives for foods, drugs, devices, and cosmetics”). The literature uses a number of terms (e.g., “personal care products”) that may include cosmetics but may also include products in another FDA-regulated categories (e.g., drugs or devices) or outside of FDA’s authority (e.g., consumer products).

⁵³ JACQUELINE HINER, IBISWORLD, INC., *COSMETIC & BEAUTY PRODUCTS MANUFACTURING IN THE UNITED STATES, INDUSTRY AT A GLANCE* 4 (2019).

⁵⁴ See *Voluntary Registration of Cosmetic Product Establishments*, 21 C.F.R. pt. 710 (2021).

⁵⁵ HINER, *supra* note 53, at 4.

⁵⁶ Letter from Anna K. Abram, Deputy Comm’r for Pol’y, Plan., Legis. & Analysis, U.S. FDA, to Rep. Frank Pallone, Jr., Ranking Member, Energy & Com. Comm., House of Representatives 2 (June 30, 2017), <https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/FDA%20Response%20to%20Rep.%20Pallone%20on%20Cosmetic%20Imports.pdf> [<https://perma.cc/MGP2-PRZM>].

⁵⁷ *Id.*

Although the industry has grown substantially since 1938 when the FDCA was enacted,⁵⁸ cosmetic law has largely remained unchanged.⁵⁹

C. *Why Federal Cosmetic Reform Is Needed*

1. Federal Cosmetic Law & Regulation

a. *Overview*

The FDCA establishes the basic regulatory framework for cosmetics.⁶⁰ While there have been a few amendments to the cosmetic provisions since 1938, the basic regulatory structure based on post-market regulation has not changed⁶¹: The FDCA prohibits the adulteration and misbranding of cosmetics.⁶² In contrast, Congress has amended, and generally expanded, FDA's powers concerning food, drugs, and medical devices—the original major product categories in the 1938 Act.⁶³

⁵⁸ See HINER, *supra* note 53 (estimating the 2019 revenue and profit for the cosmetics and beauty products manufacturing industry); GILBERT VAIL, A HISTORY OF COSMETICS IN AMERICA 137 (1947) (identifying the value of the cosmetic industry production in 1937 as \$132,336,481 and in 1939 as \$147,465,585); see also *CPI Inflation Calculator*, U.S. BUREAU OF LAB. STATS., <https://data.bls.gov/cgi-bin/cpicalc.pl> (last visited Jan. 17, 2022) (indicating that the value of \$1 at end of 1938 has same buying power as \$18.68 in January 2021).

⁵⁹ Statement from FDA Commissioner, *supra* note 1 (“Our program for cosmetics also has remained small despite the industry’s significant expansion and global supply chain.”).

⁶⁰ Federal Food, Drug, and Cosmetic Act (FDCA) §§ 201(i), 301, 601-603, 752, 21 U.S.C. §§ 321(i), 331, 361-363, 379s. This Article does not address other laws that set forth requirements for cosmetics such as the Federal Trade Commission Act. See, e.g., Federal Trade Commission Act, 15 U.S.C. §§ 41-58.

⁶¹ Color additives, which must be approved before use, are the exception to this stagnation. See sources cited *supra* note 51. Congress has made amendments to address color additives, the Poison Prevention Packaging Act, and plastic microbeads. See generally Color Additive Amendments of 1960, Pub. L. No. 86-618, sec. 102(c)(1), (2), §§ 601(e), 602(e), 74 Stat. 397, 398 (codified as amended at 21 U.S.C. §§ 361(e), 362(e)); *id.* sec. 103(a)(3), repealing § 604 (repealing 21 U.S.C. § 364); Poison Prevention Packaging Act of 1970, Pub. L. No. 91-601, sec. 7(f), § 602, 84 Stat. 1670, 1673 (codified as amended at 21 U.S.C. § 362(f)); Microbead Free Waters Act of 2015, Pub. L. No. 114-114, sec. 2, § 301, 129 Stat. 3129, 3129 (codified at 21 U.S.C. § 331(ddd)) (prohibiting “manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads”). In addition, Congress has added the preemption and savings provisions in section 752 of the FDCA (21 U.S.C. § 379s), which are discussed in Section I.E.2. The Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, sec. 412, § 752, 111 Stat. 2296, 2373, 2376 (codified at 21 U.S.C. § 379s).

⁶² FDCA §§ 301, 601-602, 21 U.S.C. §§ 331, 361-362.

⁶³ See, e.g., FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011); Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539; Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780; see also Robert M. Califf, Jonathan McCall & Daniel B. Mark, Editorial, *Cosmetics, Regulations, and the Public Health: Understanding the Safety of Medical and Other Products*, 177 JAMA INTERNAL MED. 1080,

In addition, FDA's cosmetic regulations are limited.⁶⁴ The regulations include various labeling requirements,⁶⁵ and provide that the use of eleven specified ingredients or ingredient-types in cosmetics is subject to restrictions or renders cosmetics adulterated.⁶⁶

b. *Limitations*

The limitations of current cosmetic laws and regulations are well-documented,⁶⁷ and therefore only briefly summarized here. First, there is no pre-market approval requirement for cosmetics.⁶⁸ This stands in contrast to drugs, certain devices, and food additives, which Congress has specified require premarket approval.⁶⁹ While the cosmetic industry has created and funded a Cosmetic Ingredient Review ("CIR"), which reviews the safety of cosmetic ingredients,⁷⁰ the CIR suffers from several significant limitations.⁷¹ For example, compliance with CIR recommendations is voluntary, as the program's findings do not bind the industry.⁷² In addition, the CIR has only reviewed a fraction of the ingredients used in cosmetics, cosmetic safety information is often limited, and the CIR "generally focuses on the ingredients' potential to

1080 (2017) ("Although FDA oversight of drugs and medical devices has been substantially strengthened by later legislation, the lack of similar enhancements for cosmetics means that the cosmetic industry remains largely self-regulated."). *Compare* FDCA, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (originally codified at 21 U.S.C. §§ 301-392 (Supp. 4 1938)), with 21 U.S.C. §§ 301-399i (2018).

⁶⁴ See 21 C.F.R. pts. 700-740 (2021).

⁶⁵ See *id.* pt. 701 (establishing requirements for cosmetic labeling); *id.* pt. 740 (establishing requirements for cosmetic product warning statements).

⁶⁶ See *id.* pt. 700; *id.* § 250.250.

⁶⁷ See, e.g., Boyd, *supra* note 6, at 323 n.363 (listing scholars and commentators who have proposed or supported reforms).

⁶⁸ As noted earlier, color additives require approval. See FDCA § 721, 21 U.S.C. § 379e; *id.* § 402(c), 21 U.S.C. § 342(c); *id.* § 601(e), 21 U.S.C. § 361(e).

⁶⁹ *Id.* § 409, 21 U.S.C. § 348 (requiring premarket approval of food additives); *id.* § 505, 21 U.S.C. § 355 (requiring premarket approval of new drugs); *id.* §§ 513(a)(1)(C), 515, 21 U.S.C. §§ 360c(a)(1)(C), 360e (requiring premarket approval of class III devices).

⁷⁰ *About the Cosmetic Ingredient Review*, COSM. INGREDIENT REV., <https://www.cir-safety.org/about> [<https://perma.cc/22R5-B862>] (last visited Jan. 17, 2022); *How Does CIR Work?*, COSM. INGREDIENT REV., <https://www.cir-safety.org/how-does-cir-work> [<https://perma.cc/CNN9-W9KD>] (last visited Jan. 17, 2022).

⁷¹ See, e.g., Rajiv Shah & Kelly E. Taylor, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk*, 23 *FORDHAM ENV'T L. REV.* 203, 204 (2011); Valerie J. Watnick, *The Missing Link: U.S. Regulation of Consumer Cosmetic Products to Protect Human Health and the Environment*, 31 *PACE ENV'T L. REV.* 594, 605-06 (2014) ("[E]xperts have estimated that only between 11% and 13% of ingredients used in cosmetics have actually been subject to CIR analysis.").

⁷² See Jacqueline A. Greff, *Regulation of Cosmetics That Are Also Drugs*, 51 *FOOD & DRUG L.J.* 243, 246 (1996).

cause short-term dermatological reactions . . . not their potential to cause long-term health problems.”⁷³

With no premarket approval authority for cosmetics, FDA relies on postmarket compliance and enforcement activities to regulate cosmetics. These, however, are also limited. For example, as noted above, the number of cosmetic establishments is unknown because establishment registration is voluntary, unlike for drug, device, tobacco product, and food facilities.⁷⁴ This complicates regulation because FDA may not even know that a firm is manufacturing cosmetics. FDA inspections of cosmetic establishments are infrequent.⁷⁵ Unlike for some other major product categories, the FDCA does not specify the frequency of inspections for cosmetic establishments.⁷⁶ Furthermore, in the unlikely event that FDA inspects a cosmetic establishment, FDA’s authority, unlike that for other product categories, does not generally include the inspection of records.⁷⁷ Moreover, its GMPs for cosmetics are simply draft guidance.⁷⁸ Cosmetics also differ from the other major product categories because their producers are not subject to mandatory adverse event reporting in any circumstance.⁷⁹ Unlike drugs, cosmetics are not subject to mandatory ingredient

⁷³ Shah & Taylor, *supra* note 71, at 204; see Ivan J. Boyer, Wilma F. Bergfeld, Bart Heldreth, Monice M. Fiume & Lillian J. Gill, *The Cosmetic Ingredient Review Program—Expert Safety Assessments of Cosmetic Ingredients in an Open Forum*, 36 INT’L J. TOXICOLOGY (SUPPLEMENT 2) 5S, 7S-10S (2017).

⁷⁴ See FDCA § 510, 21 U.S.C. § 360; *id.* § 415, 21 U.S.C. § 350d; *id.* § 905, 21 U.S.C. § 387e; 21 C.F.R. § 207.17 (2021); *id.* ch. 1, subch. H; *id.* pt. 807 (2020); *Voluntary Cosmetic Registration Program*, *supra* note 7.

⁷⁵ In fiscal year 2018, FDA conducted seventy-one domestic cosmetic establishment inspections and six foreign inspections. DEP’T OF HEALTH & HUM. SERVS., FISCAL YEAR 2020: JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 71 (2020), <https://www.fda.gov/media/121408/download> [<https://perma.cc/ZMC4-UM6F>].

⁷⁶ See FDCA § 421, 21 U.S.C. § 350j; *id.* § 905(g), 21 U.S.C. § 387e(g). The FDCA provides that device and drug establishments are to be inspected “in accordance with a risk-based schedule” established by the Secretary of Health and Human Services. *Id.* § 510(h)(2)(A), 21 U.S.C. § 360(h)(2)(A).

⁷⁷ *Id.* § 703, 21 U.S.C. § 373; *id.* § 704, 21 U.S.C. § 374; *id.* § 414(a)(1), 21 U.S.C. § 350c(a)(1); 21 C.F.R. pts. 110-11; *id.* pts. 210-11, 225-26; *id.* § 700.27(c); *id.* pt. 820; GOOD MANUFACTURING PRACTICES, *supra* note 9, at 3-4; Statement from FDA Commissioner, *supra* note 1; see also FDA RECORDS ACCESS AUTHORITY, *supra* note 8, at 3-4.

⁷⁸ GOOD MANUFACTURING PRACTICES, *supra* note 9, at 1.

⁷⁹ FDCA § 761, 21 U.S.C. § 379aa-1 (mandating reporting for adverse events associated with dietary supplements); *id.* § 760, 21 U.S.C. § 379aa (mandating reporting for adverse events associated with nonprescription drugs); *id.* § 417, 21 U.S.C. § 350f (mandating reporting for reportable foods); 21 C.F.R. § 314.80 (mandating “reporting of adverse drug experiences”); *id.* pt. 803 (mandating adverse event reporting for medical devices); *Using Adverse Event Reports*, *supra* note 10; see also *Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities*, U.S. FDA (May 5, 2020), <https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities> [<https://perma.cc/D8E5-RGBV>].

listing.⁸⁰ Cosmetics for professional use only, unlike drugs and many foods, are also not required to have ingredient labeling.⁸¹ In addition, “FDA has no authority under the [FDCA] to order a recall of a cosmetic,” and instead must rely on a request, which the company may or may not heed.⁸² Moreover, in court actions, the government bears the burden of proving that the cosmetic violates the FDCA.⁸³

In addition, FDA’s budget for cosmetics is limited and insufficient to regulate cosmetics adequately. In an editorial, former FDA Commissioner Robert M. Califf, Jonathan McCall, and Daniel B. Mark, wrote that in comparison to the global cosmetic industry, FDA’s Office of Cosmetics and Colors “is tiny . . . and, with a budget of around \$13 million for Fiscal Year 2017, chronically underfunded, even considering its limited responsibilities and scope of authority.”⁸⁴ The limitations of the current regulatory system are concerning because they may put the health and safety of those who use or are exposed to cosmetics at risk.

⁸⁰ FDCA § 510(j), 21 U.S.C. § 360(j); 21 C.F.R. § 207.49.

⁸¹ Fair Packaging and Labeling Act, Pub. L. No. 89-755, 80 Stat. 1296 (1966) (codified as amended at 15 U.S.C. §§ 1451-1461); FDCA § 403(i), (q), 21 U.S.C. § 343(i), (q); *id.* § 502(e), 21 U.S.C. § 352(e); 21 C.F.R. § 701.3.

⁸² *FDA Recall Policy for Cosmetics*, *supra* note 7.

⁸³ FDCA §§ 301, 601, 602, 21 U.S.C. §§ 331, 361, 362; KATHRYN B. ARMSTRONG & JENNIFER A. STAMAN, CONG. RSCH. SERV., R43609, ENFORCEMENT OF THE FOOD, DRUG, AND COSMETIC ACT: SELECT LEGAL ISSUES 17 (2018) (identifying elements that the government must prove under the FDCA for criminal convictions); *cf.* FDCA § 402(f), 21 U.S.C. § 342(f) (placing burden of proof on the government to establish “that a dietary supplement is adulterated”); A. Wes Siegner, Jr., *The Food & Drug Administration’s Actions on Ephedra and Androstenedione: Understanding Their Potential Impacts on the Protections of the Dietary Supplement Health and Education Act*, 59 FOOD & DRUG L.J. 617, 620 n.18 (2004) (stating that “courts historically have held that FDA bears the burden of proof in any seizure actions on the issue of adulteration”).

⁸⁴ Califf et al., *supra* note 63, at 1080-81 (arguing that “Congress should provide the agency with an adequate budget to fulfill its existing responsibilities, which it mandates”); *see also* U.S. FDA, EXECUTIVE SUMMARY: FDA FY 2017 BUDGET—ALL PURPOSE TABLE (2017), <https://www.fda.gov/media/96229/download> [<https://perma.cc/S6DE-9WZL>].

For comparison, the 2017 FDA budget for human drugs was \$1.3 billion and for medical devices was \$441 million. *HHS FY 2018 Budget in Brief - FDA*, U.S. DEP’T OF HEALTH & HUM. SERVS. (May 23, 2017), <https://www.hhs.gov/about/budget/fy2018/budget-in-brief/fda/index.html#ftno1> [<https://perma.cc/2RHT-NKJG>]. The budget for foods, which includes the cosmetics budget as FDA does not have a separate center for cosmetics, was \$993 million. *Id.*; *What We Do at CFSAN*, U.S. FDA (Sept. 16, 2019), <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/WhatWeDo/default.htm> [<https://perma.cc/C329-GB3A>].

2. Potential Health & Safety Risks

Cosmetics, their ingredients, and their components may pose potential health hazards and risks.⁸⁵ This Section highlights a few of the potential issues and areas of concern. It provides examples of cosmetic products, ingredients, and potential contaminants that FDA has addressed in warning letters or referenced in consumer information.

However, it is important to note that there is a dearth of information about the safety of many cosmetics and cosmetic ingredients, and the long-term safety of many cosmetic ingredients is unknown.⁸⁶ Furthermore, even when ingredients used in cosmetics have been studied and found to cause ill effects, “the ingredient may not cause the same problems in actual use in a cosmetic” due to differences in the amount, use, and absorption.⁸⁷ For example, “[p]arabens are commonly used as preservatives in cosmetics.”⁸⁸ The Environmental Working Group (“EWG”) has noted that “scientific studies suggest that parabens can disrupt hormones in the body and harm fertility and reproductive organs, affect birth outcomes, . . . increase the risk of cancer[, and] . . . cause skin irritation.”⁸⁹ FDA, however, has stated that the agency “do[es] not have information showing that parabens *as they are used in cosmetics* have an effect on human health.”⁹⁰ As another example, FDA has noted that 1,4-dioxane—a byproduct of certain

⁸⁵ For discussions of potential ingredients of concern and health risks in the legal literature, see, for example, Anastasia De Paz, *The Cosmetic Regime Needs a Makeover: Advocating to Empower the FDA Through the Safe Cosmetics Act of 2011*, 31 TEMP. J. SCI. TECH. & ENV'T L. 337, 340-42 (2012); Katherine Drabiak, *Dying to Be Fresh and Clean? Toxicants in Personal Care Products, the Impact on Cancer Risk, and Epigenetic Damage*, 35 PACE ENV'T L. REV. 75, 83-85 (2017); Rachael Rawlins, *Teething on Toxins: In Search of Regulatory Solutions for Toys and Cosmetics*, 20 FORDHAM ENV'T L. REV. 1, 6-7 (2009); Shah & Taylor, *supra* note 71, at 208-14; Donald R. Johnson, Note, *Not in My Makeup: The Need for Enhanced Premarket Regulatory Authority over Cosmetics in Light of Increased Usage of Engineered Nanoparticles*, 26 J. CONTEMP. HEALTH L. & POL'Y 82, 82-85 (2009); and Grace Wallack, Note, *Rethinking FDA's Regulation of Cosmetics*, 56 HARV. J. LEGIS. 311, 323-31 (2019).

⁸⁶ See, e.g., *Cosmetics*, AM. CANCER SOC'Y (May 28, 2014), <https://www.cancer.org/cancer/cancer-causes/cosmetics.html> [<https://perma.cc/4FFP-T6QU>].

⁸⁷ *Id.*

⁸⁸ *Parabens in Cosmetics*, U.S. FDA (Aug. 24, 2020), https://www.fda.gov/cosmetics/cosmetic-ingredients/parabens-cosmetics#are_parabens_safe [<https://perma.cc/2EQQ-HD82>].

⁸⁹ Tasha Stoiber, *What Are Parabens, and Why Don't They Belong in Cosmetics?*, ENV'T WORKING GRP. (Apr. 9, 2019), <https://www.ewg.org/californiacosmetics/parabens> [<https://perma.cc/DQY3-FM7V>].

⁹⁰ *Parabens in Cosmetics*, *supra* note 88 (emphasis added); see also Molly Wanner & Neera Nathan, *Clean Cosmetics: The Science Behind the Trend*, HARV. HEALTH BLOG (Mar. 12, 2019, 2:19 PM), <https://www.health.harvard.edu/blog/clean-cosmetics-the-science-behind-the-trend-2019030416066> [<https://perma.cc/VCV7-U4Z4>] (“Many of the studies showing a direct relationship between [parabens] and hormonal dysregulation have been performed in animals rather than in humans, and at higher doses than people would typically be exposed to through a cosmetic or personal care product.”).

ingredient manufacturing and a “potential human carcinogen”—may occur in cosmetics.⁹¹ While FDA has stated that it “agree[s] that levels of 1,4-dioxane as a contaminant in cosmetic products should be reduced to the lowest levels possible using good manufacturing practices,” it has declined to issue a rule providing that cosmetics with detectable concentrations of 1,4-dioxane are adulterated, stating in part, that there is a “lack of data demonstrating that any detectable concentration of 1,4-dioxane would render a cosmetic injurious to users under its conditions of use.”⁹²

Cosmetics may contain irritants and allergens. FDA has compiled a list of five classes “of common allergens found in some cosmetic products.”⁹³ FDA notes that “[a]llergic reactions can range in severity, but may include hives, itchy skin, a rash, flaking or peeling skin, facial swelling, irritation of the eyes, nose and mouth, wheezing, and anaphylaxis.”⁹⁴ One of the classes of allergens is dyes, which includes p-phenylenediamine (“PPD”).⁹⁵ FDA has noted that the use of black henna is potentially harmful because it often contains a coal-tar hair dye with PPD, which “can cause dangerous skin reactions in some people.”⁹⁶ FDA has written that consumers have reported “injuries to the skin from . . . products marketed as ‘black henna.’”⁹⁷

Cosmetics may contain ingredients or nonfunctional constituents, which may pose other health risks. For example, FDA has issued warning letters to two companies regarding hair smoothing products it alleged had “methylene glycol, the liquid form of formaldehyde, which, under the conditions of use prescribed in the labeling, release[d] formaldehyde.”⁹⁸ FDA has noted that “[f]ormaldehyde is a highly reactive chemical that readily reacts with biological tissues, particularly the mucous tissues lining the respiratory tract and the eyes” and “is

⁹¹ See *1,4-Dioxane in Cosmetics: A Manufacturing Byproduct*, U.S. FDA (Aug. 24, 2020), <https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct> [<https://perma.cc/QT5C-C5L5>]; see also Wanner & Nathan, *supra* note 90.

⁹² Letter from Linda M. Katz, Dir., FDA Off. Cosms. & Colors, to Sens. Charles E. Schumer & Kirsten Gillibrand 1-2 (Dec. 19, 2017), <https://www.regulations.gov/document/FDA-2017-P-2365-0006> [<https://perma.cc/XD47-BW5N>].

⁹³ *Allergens in Cosmetics*, U.S. FDA (Nov. 12, 2020), <https://www.fda.gov/cosmetics/cosmetic-ingredients/allergens-cosmetics#common> [<https://perma.cc/6JRR-FHTB>].

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Temporary Tattoos, Henna/Mehndi, and “Black Henna”: Fact Sheet*, U.S. FDA (Aug. 24, 2020), <https://www.fda.gov/cosmetics/cosmetic-products/temporary-tattoos-henna-mehndi-and-black-henna-fact-sheet> [<https://perma.cc/C5SN-DNY3>].

⁹⁷ *Id.*

⁹⁸ U.S. FDA, Ctr. for Food Safety & Applied Nutrition Off. of Compliance, Warning Letter on Brazilian Blowout (Aug. 22, 2011) (archived at <https://web.archive.org/web/20170327183305/https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm270809.htm> on Mar. 27, 2017); U.S. FDA, Fla. Dist. Off., Warning Letter to Van Tibolli Beauty Corp. (Sept. 2, 2015) [hereinafter Warning Letter Van Tibolli Beauty Corp.] (archived at <https://perma.cc/AA28-U2NY> on Jan. 23, 2020).

a recognized carcinogen.”⁹⁹ In 2019, FDA also advised consumers to stop using certain cosmetic products after it said that samples of the products tested positive for asbestos, a known carcinogen, during FDA’s survey of talc-containing cosmetics.¹⁰⁰ In addition, through guidance, FDA has sought to educate and encourage “manufacturers to continue to follow or improve on *voluntary* good manufacturing practices that limit trace amount of lead as an impurity” in cosmetic lip products and externally applied cosmetics.¹⁰¹

Cosmetics may also contain microbial contaminants. For example, FDA issued several warning letters alleging, among other things, that certain cosmetic products were “adulterated due to microbial contamination posing a potential health risk for the uses recommended in the labeling.”¹⁰²

D. *Federal Cosmetic Reform Bills*

The FDA Commissioner and CFSAN Director have stated that “[t]o significantly shift the safety paradigm of cosmetics in the U.S., [FDA] would need to work with stakeholders, including Congress, to modernize the outdated regulatory framework.”¹⁰³ In recognition of the limitations of the current framework, legislators have introduced bills during recent Congresses to reform the regulation of cosmetics. This Section provides a high-level overview of several bills that would reform the general regulatory framework for cosmetics: The Personal Care Products Safety Act, Senate Bill 2100; the Cosmetic Safety Enhancement Act of 2019, House Bill 5279; the Safe Cosmetics and Personal Care Products Act of 2019, House Bill 4296; the Personal Care Products Safety Act, Senate Bill 726; the FDA Cosmetic Safety and Modernization Act, Senate

⁹⁹ Warning Letter Van Tibolli Beauty Corp., *supra* note 98.

¹⁰⁰ *FDA Advises Consumers*, *supra* note 4; *Talc*, U.S. FDA (Aug. 18, 2020) (website updated; cited for historical fact and archived at <https://perma.cc/W4FV-EQ6A> on Jan. 22, 2020).

¹⁰¹ *Supporting Document for Recommended Maximum Lead Level in Cosmetic Lip Products and Externally Applied Cosmetics*, U.S. FDA (Aug. 24, 2020), <https://www.fda.gov/cosmetics/cosmetics-guidance-documents/supporting-document-recommended-maximum-lead-level-cosmetic-lip-products-and-externally-applied> [<https://perma.cc/X6UA-PG5E>] (emphasis added). Exposure to lead is cumulative and impacts multiple body systems. WORLD HEALTH ORG., EXPOSURE TO LEAD: A MAJOR PUBLIC HEALTH CONCERN 1 (2019), <https://apps.who.int/iris/bitstream/handle/10665/329953/WHO-CED-PHE-EPE-19.4.7-eng.pdf?ua=1> [<https://perma.cc/Y6Q7-GAV2>]. The World Health Organization notes that “[c]hildren are particularly vulnerable to the neurotoxic effects of lead, and even relatively low levels of exposure can cause serious and, in some cases, irreversible neurological damage.” *Id.* In addition, “[e]xposure of pregnant women to high levels of lead can cause miscarriage, stillbirth, premature birth and low birth weight, as well as minor malformations.” *Id.* at 4.

¹⁰² *Warning Letters Cite Cosmetics as Adulterated Due to Microbial Contamination*, U.S. FDA (Sept. 11, 2020), <https://www.fda.gov/cosmetics/warning-letters-related-cosmetics/warning-letters-cite-cosmetics-adulterated-due-microbial-contamination> [<https://perma.cc/U3WZ-EUKJ>].

¹⁰³ Statement from FDA Commissioner, *supra* note 1.

Bill 2003; and the Cosmetic Modernization Amendments of 2017, House Bill 575.¹⁰⁴

The bills have several regulatory features in common. For example, all the bills would require the reporting of serious adverse events, compliance with GMP, and the registration of cosmetic establishments.¹⁰⁵ However, even where the bills include the same general type of regulatory requirements, there are substantial differences.

While all of the bills would require establishment registration, the details of what the bills would require vary significantly. For example, the establishments that would be required to register differ. Senate Bill 2100 would require facilities manufacturing or processing cosmetic products or formulations distributed in the United States to register.¹⁰⁶ Senate Bill 2003 would provide that “the manufacturer or distributor whose name appears on the label of a cosmetic marketed in the United States” shall be required “to register all facilities engaged in manufacturing of such cosmetic.”¹⁰⁷ In contrast, House Bill 5279 would

¹⁰⁴ Personal Care Products Safety Act, S. 2100, 117th Cong. (2021); Cosmetic Safety Enhancement Act of 2019, H.R. 5279, 116th Cong. (2019); Safe Cosmetics and Personal Care Products Act of 2019, H.R. 4296, 116th Cong. (2019); Personal Care Products Safety Act, S. 726, 116th Cong. (2019); FDA Cosmetic Safety and Modernization Act, S. 2003, 115th Cong. (2017); Cosmetic Modernization Amendments of 2017, H.R. 575, 115th Cong. (2017). While House Bill 5279 and Senate Bill 726 are related bills, this Article addresses them separately because they vary, including with respect to preemption. Senate Bill 2100 is essentially identical to Senate Bill 726 with respect to preemption. *Compare* S. 2100, *with* S. 726.

In addition to the bills discussed in the text above, several more narrowly tailored bills have been introduced: House Bill 1816 would require the labeling of talc in children’s cosmetics unless the manufacturer attests in writing that the talc is from an asbestos-free mine and demonstrates that the talc is asbestos free. Children’s Product Warning Label Act of 2019, H.R. 1816, 116th Cong. (2019). House Bill 5017 would establish standards for the use of the term “natural” on cosmetic labeling. Natural Cosmetics Act, H.R. 5017, 116th Cong. (2019). Senate Bill 2886 and House Bill 5141 would prohibit cosmetic animal testing. Humane Cosmetics Act of 2019, S. 2886, 116th Cong. (2019); Humane Cosmetics Act of 2019, H.R. 5141, 116th Cong. (2019). Senate Bill 2047 and House Bill 3990 would “ban the use of intentionally added perfluoroalkyl or polyfluoroalkyl substances in cosmetics.” No PFAS in Cosmetics Act, S. 2047, 117th Cong. (2021); No PFAS in Cosmetics Act, H.R. 3990, 117th Cong. (2021). Senate Bill 872 would require labeling of cosmetics for professional use; support research on safer cosmetic design and “promote the use of safer alternatives in cosmetics” with priority to grant applicants focused on “professional cosmetic products used by nail, hair, and beauty salon workers,” and “women and girls of color,” and expand support of “research on health disparities related to cosmetics impacting communities of color.” Environmental Justice For All Act, S. 872, 117th Cong. §§ 23, 24, 27 (2021). And House Bill 5548 would require the Environmental Protection Agency to study “the presence of . . . personal care products in sources of drinking water.” Water, Cosmetics, and Unwanted Pharmaceuticals Study Act, H.R. 5548, 115th Cong. (2018). As this Article’s focus is broader cosmetic reform, these narrow bills are not examined in detail. In addition, due to the evolving nature of the legislative landscape not all recent bills are discussed in this Article.

¹⁰⁵ S. 2100; H.R. 5279; H.R. 4296; S. 726; S. 2003; H.R. 575.

¹⁰⁶ S. 2100 § 101, at 6.

¹⁰⁷ S. 2003 § 5, at 9.

require the registration of cosmetic manufacturing and processing facilities and packing or holding facilities.¹⁰⁸ As another example, Senate Bill 2100 would establish registration fees and specific fee setting,¹⁰⁹ while House Bill 4296 would provide for the payment of registration fees and the development of a fee schedule,¹¹⁰ and House Bill 575 would not explicitly provide for registration fees.¹¹¹ As a third example, House Bill 5279 would prohibit the failure to register, provide certain information, or update the information.¹¹² It would also establish procedures for the Secretary to cancel a facility's registration if the Secretary has reasonable grounds to believe that the registration is incomplete or inaccurate.¹¹³ In contrast, House Bill 575 provides that the registration must "be maintained as current and accurate" and would prohibit failing to register a cosmetic establishment or failing to maintain the registration,¹¹⁴ however, it states that the Secretary "shall not suspend or revoke a registration."¹¹⁵

The bills also vary in how they address the issue of cosmetic safety.¹¹⁶ For example, the bills would require FDA to review cosmetics, cosmetic ingredients, or nonfunctional constituents for safety. The process for identifying substances for review, the number of substances to be reviewed, and timing for review, if any, vary among the bills. It is unclear how many substances FDA would be able to realistically review and make final safety determinations for, under the proposed frameworks.¹¹⁷ Some of the bills would specify the number of

¹⁰⁸ H.R. 5279 § 101, at 7-9.

¹⁰⁹ S. 2100 § 202, at 80-89.

¹¹⁰ H.R. 4296 § 2, at 7-8, 11.

¹¹¹ See H.R. 575, 115th Cong. (2017).

¹¹² H.R. 5279 § 114, at 92-93.

¹¹³ *Id.* § 101, at 12-13.

¹¹⁴ H.R. 575 § 4, at 6, § 11, at 27.

¹¹⁵ *Id.* § 4, at 6.

¹¹⁶ In addition, three of the bills would specifically address the safety of products for children, pregnant women, and other vulnerable populations. See H.R. 5279 § 102, at 34-35; H.R. 4296, 116th Cong. § 2, at 7 (2019); S. 726, 116th Cong. § 102, at 28, § 106, at 55 (2019).

¹¹⁷ FDA has confronted a similar problem in the Over-the-Counter ("OTC") Drug Review. See *Over-the-Counter Drugs: Proposal Establishing Rule Making Procedures for Classification*, 37 Fed. Reg. 85 (Jan. 5, 1972) (to be codified at 21 C.F.R. pt. 130); *Drug Applications for Over-the-Counter (OTC) Drugs*, U.S. FDA (Mar. 31, 2020), <https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs> [<https://perma.cc/PB9S-6VXX>] (indicating that "there are over 300,000 marketed OTC drug products"); see also *Coronavirus Aid, Relief, and Economic Security (CARES) Act*, Pub. L. No. 116-136, §§ 3851-3853, 134 Stat. 281, 435-54 (2020) (codified in scattered sections of 21 U.S.C.) (reforming the OTC Drug Review process); *Why Did the OTC Drug Review Need to Be Reformed?*, Dropdown in *Over-the-Counter (OTC) Drug Review: OCT Monograph Reform in the CARES Act*, U.S. FDA (Oct. 1, 2021), <https://www.fda.gov/drugs/over-counter-otc-nonprescription-drugs/over-counter-otc-drug-review-otc-monograph-reform-cares-act#status> [<https://perma.cc/269L-4ZWA>] (noting that prior to the CARES Act, "[d]espite FDA's successes in providing consumers with access to a wide variety of safe and effective

substances to be reviewed each year, but these numbers would constitute only a small fraction of the number of cosmetic ingredients.¹¹⁸ For example, Senate Bill 2100 would require FDA to review at least five cosmetics or nonfunctional constituents each year.¹¹⁹ The number of cosmetic ingredients is unknown because, as noted above, cosmetics are not subject to mandatory ingredient listing under current law.¹²⁰ The number of ingredients likely exceeds the approximately 6,000 ingredients that the cosmetic industry has submitted to FDA under the Voluntary Cosmetic Registration Program.¹²¹ Some sources suggest that there may be over 20,000 cosmetic ingredients.¹²² Despite the differences among the regulatory frameworks that the bills would create, none would require *premarket* approval of cosmetic ingredients and constituents.¹²³

There are also significant differences among the bills with respect to other aspects of the regulatory frameworks that they would create. For example, only five of the six bills would require the submission of ingredient statements.¹²⁴ In addition, only three of the bills discussed here would give FDA the authority to inspect a variety of cosmetic records,¹²⁵ four would give FDA the authority to mandate a recall of a cosmetic under certain circumstances,¹²⁶ and four would require ingredient labeling for professional-use cosmetics.¹²⁷ Thus, not all of the

OTC monograph drugs, challenges with the nearly 50-year old OTC Drug Review process became apparent,” including that “FDA lacked adequate resources to devote to [the] rulemaking process” and “[d]elays in finalizing monographs”) (choose “Why did the OTC drug review need to be reformed?” from dropdown).

¹¹⁸ See, e.g., S. 2100, 117th Cong. § 102, at 23-24 (2021).

¹¹⁹ *Id.*

¹²⁰ See *supra* note 80 and accompanying text.

¹²¹ See Boyer et al., *supra* note 73, at 75; *Voluntary Cosmetic Registration Program*, U.S. FDA (Aug. 24, 2020), <https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program> [<https://perma.cc/XC8P-T7LU>].

¹²² See Boyer et al., *supra* note 73, at 75 (stating that the latest edition of *International Cosmetic Ingredient Dictionary and Handbook* lists over 21,000 ingredients); see also U.S. FDA, PROGRAM 7329.001, COMPLIANCE PROGRAM GUIDANCE MANUAL, ch. 29 (2008) (archived at <https://web.archive.org/web/20090528173701/http://www.cfsan.fda.gov/~acrobat/cp29001.pdf> on May 28, 2009).

¹²³ See S. 2100; H.R. 5279, 116th Cong. (2019); H.R. 4296, 116th Cong. (2019); S. 726, 116th Cong. (2019); S. 2003, 115th Cong. (2017); H.R. 575, 115th Cong. (2017).

¹²⁴ Compare S. 2100 § 101, H.R. 5279 § 101, H.R. 4296 § 2, at 44-46, S. 726 § 101, and H.R. 575 § 2 at 8-10, with S. 2003.

¹²⁵ Compare S. 2100 § 105, H.R. 5279 § 105, and S. 726 § 105, with S. 2003 § 2, at 4-5, H.R. 4296, § 2, and H.R. 575. Two are more narrow in scope: Senate Bill 2003 would only allow for the inspection of records related to serious adverse event reports. S. 2003 § 2, at 4-5 (proposing section 762(e)). House Bill 4296 would provide for the provision of records related to certain supply chain information. H.R. 4296 § 2, at 52-54 (proposing section 620(f)).

¹²⁶ Compare S. 2100 § 105, H.R. 5279 § 105, H.R. 4296 (proposing section 620(d)), and S. 726 § 105, with S. 2003, and H.R. 575.

¹²⁷ Compare S. 2100 § 106, at 55-56, H.R. 5279 § 106, at 75, H.R. 4296 § 2, at 13-21, and S. 726 § 106, at 56, with S. 2003, and H.R. 575.

bills would fill the gaps in the current regulatory system. Indeed, Congress's and FDA's ability to institute meaningful reform may be hindered by current information deficits that limit the information available to FDA about even the most basic facts regarding the industry, such as who is manufacturing what and where.¹²⁸

Cosmetic reform should, at a minimum, give FDA the authority to regulate cosmetics meaningfully. For example, FDA cannot inspect facilities if it does not even know that the facilities exist and manufacture cosmetics. Its ability to conduct meaningful inspections of cosmetic manufacturing is limited if it does not have the authority to inspect manufacturing records. It cannot require compliance with GMP if the GMP is set forth in nonbinding draft guidance and guidelines. It cannot adequately monitor the safety of cosmetics if manufacturers do not have to report serious adverse events. And it cannot monitor the safety of ingredients that it does not know are being used in cosmetics. If enacted, the proposed reforms, coupled with information from tort litigation, may help to fill some of these information deficits, laying the groundwork for a better regulatory system for cosmetics and, ultimately, safer cosmetics for consumers.

¹²⁸ The bills vary in terms of their preemption and saving provisions, if any. For example, the publicly available text of House Bill 5279 contains a saving clause, but no preemption provision. H.R. 5279, § 113 (providing that nothing in the bill, "nor any standard, rule, requirement, regulation, adverse event report, safety assessment, safety determination, scientific assessment, or order issued or implemented pursuant to such amendments, shall be construed to modify or otherwise affect, preempt, or displace any cause of action or State . . . law creating a remedy for civil relief . . . , whether statutory or based in common law"). However, as noted earlier, Representative Pallone acknowledged at a markup session of the Subcommittee on Health of the Energy and Commerce Committee that the lack of preemption was "a major issue." *Markup of 13 Health Bills*, *supra* note 21, at 47:24-47:26. His remarks followed those of (now former) Representative John Shimkus (Illinois), who noted he had "three main priorities," the first of which was preemption. *Id.* at 44:04. Representative Shimkus continued that the "FDA is the most competent regulator in the nation [and . . . i]f they determine something is safe or unsafe, state and local governments should respect that decision." *Id.* at 44:17-44:26; *see also Cosmetic Safety Enhancement Act Advances in US House*, *supra* note 21.

Senate Bill 2100, in contrast, has a preemption clause, which would appear to set a federal floor with respect to cosmetic safety requirements. S. 2100 § 110; *see also* S. 726 § 109. Senate Bill 2100 also contains a saving clause that states that nothing in the proposed amendments "nor any standard, rule, requirement, regulation, adverse event report, safety assessment, safety determination, scientific assessment, or order issued or implemented pursuant to such amendments, shall be construed to modify or otherwise affect, preempt, or displace any cause of action or State or Federal law creating a remedy for civil relief or criminal cause of action, whether statutory or based in common law." S. 2100 § 110, at 67; *see also* S. 726 § 109, at 62-63.

As another example, House Bill 575's preemption provision states that "[n]o State may establish or enforce a safety determination for a cosmetic or an ingredient or nonfunctional constituent of a cosmetic," but contains no saving clause. H.R. 575 § 8, at 23 (proposing section 609(e)).

E. Preemption

1. Overview

The Supremacy Clause of the United States Constitution provides that the “Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land.”¹²⁹ Thus in certain circumstances, state and local law give way to federal law.

The focus of this Article is on the preemption of state tort law claims. Express preemption occurs when Congress uses explicit statutory language—an express preemption provision—to displace state law.¹³⁰ Congress may couple express preemption provisions in a statute with savings clauses, which may “save” state and local laws from express preemption.¹³¹ At the heart of the express preemption analysis is a determination of Congress’s intent, specifically, whether Congress expressed a preemptive intent.¹³² The Court has indicated that this analysis “begin[s] with [the preemption statute’s] text.”¹³³

¹²⁹ U.S. CONST. art. VI, cl. 2.

¹³⁰ Ernest A. Young, “*The Ordinary Diet of the Law*”: *The Presumption Against Preemption in the Roberts Court*, 2011 SUP. CT. REV. 253, 270 (“Express preemption,” as that term is used in current doctrine, deals . . . with . . . the construction of statutory provisions that expressly address the preemptive effect of federal law.”). While there is no general express preemption provision in the FDCA, there are several product-specific preemption provisions, including section 379s, which deals with preemption in the cosmetic context. See FDCA § 752, 21 U.S.C. § 379s (addressing preemption in the context of “labeling or packaging of cosmetics”); *id.* § 760(h), 21 U.S.C. § 379aa(h) (addressing preemption in the context of “[s]erious adverse event reporting for non-prescription drugs”); *id.* § 916(a)(2)(A), 21 U.S.C. § 387p(a)(2)(A) (addressing preemption in the context of tobacco products); *id.* § 751, 21 U.S.C. § 379r (addressing “[n]ational uniformity for nonprescription drugs”); *id.* § 403A, 21 U.S.C. § 343-1 (addressing “[n]ational uniform nutrition labeling”); *infra* Section III.C; see also *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 n.5 (2011) (“The Hatch-Waxman Amendments contain no provision expressly pre-empting state tort claims.”); *Wyeth v. Levine*, 555 U.S. 555, 574 (2009) (“If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA’s 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, . . . Congress has not enacted such a provision for prescription drugs.”); Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1092 (2007) (noting that the “[FDCA] does not contain a generally applicable express preemption provision” and citing several cases recognizing this).

¹³¹ Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 467 (2008) (discussing Congress combining “a broad preemption clause and a seemingly contradictory savings clause”).

¹³² See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (stating that “[t]he purpose of Congress is the ultimate touchstone” in every pre-emption case” (quoting *Retail Clerks Int’l Ass’n, Loc. 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963) (alteration in original))).

¹³³ *Id.* at 484.

However, even if federal law does not *expressly* preempt state law, the Court may still find that federal law *impliedly* preempts state law.¹³⁴ Implied preemption may occur if “Congress has legislated comprehensively to occupy an entire field of regulation, leaving no room for the States to supplement federal law” (i.e., field preemption).¹³⁵ It may also occur if there is a conflict between federal and state law (i.e., conflict preemption). Conflict preemption occurs “when ‘it is *impossible* . . . to comply with both state and federal law’ or when state law ‘[is] an *obstacle* to . . . the *full purposes and objectives of Congress*.’”¹³⁶

From a plaintiff’s perspective, a court holding that her state tort law claims are preempted has the same effect regardless of the type of preemption—she is left without the potential for redress and compensation for her injury.

2. Current Cosmetic Preemption & Saving Clauses

Section 379s of the United States Code (section 752 of the FDCA) contains an express preemption provision for cosmetics. It provides that, except as provided in its exemption, product liability, and state initiative subsections:

[N]o State or political subdivision of a State may establish or continue in effect *any requirement* for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under [the FDCA], the Poison Prevention Packaging Act of 1970 or the Fair Packaging and Labeling Act.¹³⁷

¹³⁴ See *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) (“[A]n express pre-emption clause ‘does *not* bar the ordinary working of conflict pre-emption principles,’ that find implied pre-emption ‘where it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” (internal citations omitted)).

¹³⁵ *Hughes v. Talen Energy Mktg., LLC*, 136 S. Ct. 1288, 1297 (2016) (quoting *Nw. Cent. Pipeline Corp. v. State Corp. Comm’n*, 489 U.S. 493, 509 (1989)); see also *Arizona v. United States*, 567 U.S. 387, 401 (2012) (“Where Congress occupies an entire field, . . . even complementary state regulation is impermissible.”).

¹³⁶ *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 634 (2011) (Sotomayor, J., dissenting) (emphasis added) (quoting *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000)); see *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 475 (2013) (discussing impossibility preemption); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) (discussing obstacle preemption).

¹³⁷ Federal Food, Drug, and Cosmetic Act (FDCA) § 752(a), 21 U.S.C. § 379s(a) (emphasis added) (citations omitted). Furthermore, section 379s specifies that

a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under [the FDCA] for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

Id. § 752(c), 21 U.S.C. § 379s(c).

The Supreme Court has said that “[a]bsent other indication, reference to a State’s ‘requirements’ includes its common-law duties.”¹³⁸

However, here, there is indication that a reference to “any requirement” does not include certain common-law duties as the broad preemption language in section 379s is coupled with a saving clause.¹³⁹ That clause provides that “[n]othing in [section 379s] shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.”¹⁴⁰ While that saving clause appears to have been the subject of almost no discussion or debate in the legislative history,¹⁴¹ the language of the saving clause appears to clearly express Congress’s intent not to preempt State product liability actions.¹⁴² In addition, until the relatively recent cosmetic-talc litigation, the operation of the express preemption provision in light of the saving clause appears to have received little discussion.¹⁴³ In a recent opinion, the United States District Court for the District of New Jersey denied the defendant’s motion to dismiss the plaintiff’s “‘failure-to-warn and omission’ claims.”¹⁴⁴ It held that “Congress, through § 379s(d)’s saving clause, expressly preserved state product liability actions involving cosmetics.”¹⁴⁵

¹³⁸ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008).

¹³⁹ *See id.*; FDCA § 752(d), 21 U.S.C. § 379s(d).

¹⁴⁰ FDCA, § 752(d), 21 U.S.C. § 379s(d). The FDCA also provides that the Secretary of Health and Human Services may by regulation grant an exemption from preemption for a state or local labeling or packaging requirement if certain conditions are met. *Id.* § 752(b), 21 U.S.C. § 379s(b). In addition, the express preemption provision does “not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997,” an apparent reference to California’s Proposition 65. *Id.* § 752(e), 21 U.S.C. § 379s(e); *see* Safe Drinking Water and Toxic Enforcement Act of 1986, CAL. HEALTH & SAFETY CODE ch. 6.6 (West 1987) (noting that “Chapter 6.6 was added by Initiative Measure, approved by the people. Nov. 4, 1986, eff. Jan. 1, 1987”); PRESCRIPTION DRUG USER FEE REAUTHORIZATION AND DRUG REGULATORY MODERNIZATION ACT OF 1997, H.R. REP. NO. 105-310, at 117 (1997).

¹⁴¹ *See generally* S. REP. NO. 105-43 (1997) (discussing the Food & Drug Administration Modernization and Accountability Act of 1997).

¹⁴² *See id.* at 66 (“[T]he legislation explicitly provides that it shall not be construed to modify or otherwise affect the traditional product liability law of any State. Tort liability rules and requirements would remain unchanged and unaffected.”); *see also* *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000) (stating that the “saving clause” at issue in that case “at least removes tort actions from the scope of the express pre-emption clause”).

¹⁴³ For a discussion of the consideration of section 379s in several recent cosmetic-talc cases, *see infra* Section III.C.

¹⁴⁴ *Potts v. Johnson & Johnson Consumer, Inc.*, No. 20-cv-10406, 2021 WL 2177386, slip op. at *10 (D.N.J. May 28, 2021).

¹⁴⁵ *Id.*

The caselaw interpreting section 379s appears to focus on claims that are not based on state product liability law and that raise issues of whether the state labeling or packaging requirements are “different from or in addition to, or . . . otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under [the

Several courts have considered an identically worded saving clause in section 379r(e) for nonprescription drugs.¹⁴⁶ Like section 379s, section 379r was added by the Food and Drug Administration Modernization Act of 1997.¹⁴⁷ The opinions considering the operation of that saving clause appear to have accepted that the clause clearly removes from preemption “any action . . . under the product liability law of any State.”¹⁴⁸ What constitutes “product liability law” has been subject to litigation,¹⁴⁹ and courts have held that purely economic claims are not “product liability law.”¹⁵⁰ For example, in a California case involving the question of whether the plaintiff’s claims against the manufacturers of over-the-counter drugs for breach of warranty and fraud were expressly preempted, the court stated:

Under the product liability law of California, injury to the plaintiff from a defective product is an essential element of a cause of action. Liability may be imposed either for personal injury or for physical damage to property, but if the damage consists solely of economic losses, recovery on a products liability theory is unavailable.¹⁵¹

The conclusion that state tort law claims are not expressly preempted as a result of the operation of section 379s, however, does not end the inquiry, as implied preemption may still operate. Indeed, as discussed in Section III.C, both types of preemption have been raised as a defense by companies in litigation over cosmetic-talc products.¹⁵²

FDCA], the Poison Prevention Packaging Act of 1970 or the Fair Packaging and Labeling Act.” FDCA § 752(a), 21 U.S.C. § 379s(a) (citations omitted); *see Critcher v. L’Oreal U.S., Inc.*, 959 F.3d 31, 38 (2d Cir. 2020); *Ebner v. Fresh, Inc.*, 838 F.3d 958, 965 (9th Cir. 2016) (en banc); *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 757-59 (9th Cir. 2015); *Young v. L’Oréal, Inc.*, No. 21-cv-00446, 2021 WL 2295625, slip op. at *3 (S.D.N.Y. May 20, 2021); *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 319-23 (S.D.N.Y. 2017); *Bimont v. Unilever U.S., Inc.*, No. 14-cv-07749, 2015 WL 5256988, at *1 (S.D.N.Y. Sept. 9, 2015).

¹⁴⁶ Compare FDCA § 751(e), 21 U.S.C. § 379r(e), with *id.* § 752, 21 U.S.C. § 379s(d).

¹⁴⁷ See Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, sec. 412, §§ 751, 752, 111 Stat. 2296, 2374, 2376 (codified at 21 U.S.C. §§ 379r, 379s).

¹⁴⁸ See *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1286-87 (C.D. Cal. 2008); *Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 790-91 (E.D. Tex. 2008); *Kanter v. Warner-Lambert Co.*, 122 Cal. Rptr. 2d 72, 78-81 (Ct. App. 2002).

¹⁴⁹ *Carter*, 582 F. Supp. 2d at 1287; *Mills*, 581 F. Supp. 2d at 790-93; *Kanter*, 122 Cal. Rptr. 2d at 80-81.

¹⁵⁰ *Carter*, 582 F. Supp. 2d at 1287; *Mills*, 581 F. Supp. 2d at 790-93; *Kanter*, 122 Cal. Rptr. 2d at 80-81; *see also Peters v. AstraZeneca, LP*, 417 F. Supp. 2d 1051, 1055 (W.D. Wis. 2006) (stating that express preemption was not at issue in a products liability suit).

¹⁵¹ *Kanter*, 122 Cal. Rptr. 2d at 80-81 (citations omitted).

¹⁵² See *infra* Section III.C.

II. WHY THE PREEMPTION OF STATE TORT LAW MAY HINDER GENDER & RACIAL EQUITY IN THE COSMETIC CONTEXT

There is a long history of women turning to tort law in the face of regulatory inaction and failures.¹⁵³ Congress did not include cosmetics in the Pure Food and Drug Act of 1906 (“1906 Act”).¹⁵⁴ But in the years following the passage of the 1906 Act, the cosmetic industry—and concerns about the limitations of the 1906 Act and the safety of cosmetics—grew.¹⁵⁵ One cosmetic product—“Koremlu Cream”—discussed in testimony on proposed legislation to remedy some of the limitations of the 1906 Act,¹⁵⁶ for example, was the subject of lawsuits by women who alleged that the product had injured them. Some of their claims were tort claims.¹⁵⁷ Furthermore, in the over eighty years since Congress

¹⁵³ Matters of health and safety and state tort law are two areas that have been viewed as traditional domains of the states. *See, e.g.*, Barbara L. Atwell, *Products Liability and Preemption: A Judicial Framework*, 39 BUFF. L. REV. 181, 188 (1991) (“Where areas of traditional state regulation such as health and safety are involved, the Supreme Court has been particularly reluctant to preempt state law. Restraint concerning preemption of state laws addressing health and safety also extends to state tort laws.”).

¹⁵⁴ *See generally* Federal Food and Drugs Act, ch. 3915, 34 Stat. 768 (1906).

¹⁵⁵ *See* Boyd, *supra* note 6, at 310-11 (citing statistics regarding the industry’s growth and discussing the failures of the Pure Food and Drug Act of 1906).

¹⁵⁶ *See, e.g.*, CHARLES WESLEY DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD 1154 (1938).

¹⁵⁷ In its report for the fiscal year ended June 30, 1933, FDA indicated that Koremlu Cream “represented as entirely harmless and actually beneficial to the skin, contained a highly poisonous chemical—thallium acetate” and “[i]ts widespread utilization for the removal of superfluous hair caused many cases of severe injury to users before the manufacturer was forced into bankruptcy by accumulation of damage suits.” *Id.* at 26. One historian indicates that “[w]omen who had been injured [by Koremlu] sued the company and were awarded damages in excess of \$2.5 million,” but that they did not receive money after the company declared bankruptcy and failed. GWEN KAY, DYING TO BE BEAUTIFUL: THE FIGHT FOR SAFE COSMETICS 71 (2005). Although the basis of the women’s claims is not indicated, at least some plaintiffs brought torts claims against the company. *See, e.g.*, *Hillick v. E. W. Edwards & Son*, 256 N.Y.S. 313, 316 (Sup. Ct. 1932), *modified*, 257 N.Y.S. 945 (App. Div. 1932) (stating that each plaintiff “alleges that she has suffered injurious consequences from the use of ‘Koremlu Cream,’ a depilatory preparation which, it is claimed, was negligently, carelessly and illegally prepared by the defendants Kora M. Lublin ‘and/or’ Koremlu, Inc., in that it contained certain chemicals or drugs which were poisonous and dangerous to human life and health; that said Koremlu cream was misrepresented and sold by the defendant retailers E. W. Edwards & Son and Abraham & Straus, Inc., with reckless disregard of injurious consequences which might follow from its prescribed use”); *cf.* *Smith v. Denholm & McKay Co.*, 192 N.E. 631, 631-32 (Mass. 1934) (stating that plaintiff waived her tort claim and proceeded on contract claims in action “brought to recover damages for injuries arising from the use of . . . ‘Koremlu’”). For another example of a tort claim involving a cosmetic that predated the FDCA, see *Bundy v. Ey-Teb, Inc.*, 289 N.Y.S. 905, 905-07 (City Ct. 1935), which found \$2,000 for the plaintiff in an action for negligence against a corporation where “[p]laintiff suffered painful and serious injury as a result of the application to her eyes of a preparation designed to darken eyebrows or lashes and put on the market for such purpose by defendant corporation.” *Id.*

enacted the FDCA, people have continued to bring tort claims against companies making, distributing, and selling cosmetics for injuries that they allege the cosmetics caused.¹⁵⁸

This Part considers how tort liability for defective or unreasonably dangerous cosmetics may complement the federal cosmetic regulation by providing redress and compensating injured plaintiffs, encouraging manufacturers to take due care, and bringing to light information that may inform the regulation of cosmetics. This Part argues that the preemption of state tort law would have a disparate impact on women, particularly women who are members of other historically excluded groups, and may worsen gender and racial inequities. Despite its limitations, state tort law may help protect women and people of color from unsafe cosmetics, and Congress should not preempt it in the course of enacting cosmetic reform. The following Part continues by examining the plaintiffs' claims in *Ingham v. Johnson & Johnson* and exploring how many of the considerations discussed in this Part may apply in the context of talc-containing cosmetics.

A. *Why Preempting Tort Law in the Cosmetic Context May Have a Disparate Impact on Women & Particularly Women Who Are Members of Historically Excluded Groups*

The preemption of state tort law claims concerning cosmetics may have a disparate impact on women and their health and safety.¹⁵⁹ This is because, as discussed in my prior work, *Gender, Race & the Inadequate Regulation of Cosmetics*, women may be at higher risk of experiencing adverse effects from

¹⁵⁸ See, e.g., *Gober v. Revlon, Inc.*, 317 F.2d 47, 49, 52 (4th Cir. 1963) (affirming verdict in favor of consumer in action that included failure to warn claim); Third Amended Class Action Complaint at 31-35, *Friedman v. Guthy-Renker, LLC*, No. 02:14-cv-06009 (C.D. Cal. Oct. 31, 2016), ECF No. 180 (alleging, among other things, negligence, failure to warn and failure to test, and strict products liability); *In re Brazilian Blowout Litig.*, No. 10-cv-08452, 2011 WL 10962891, at *1 (C.D. Cal. Apr. 12, 2011) (stating that Plaintiffs' Second Amended Class Action Complaint alleged, among other things, negligence); Pleading at 15-16, *Frye v. L'Oreal U.S., Inc.*, No. 08-cv-00213 (N.D. Ill. Jan. 9, 2008) (alleging, among other things, strict liability and negligence per se); *Dean v. Mitchum-Thayer, Inc.*, 450 F. Supp. 1, 3 (E.D. Tenn. 1978) (granting defendant's motion for a new trial only on the issue of damages); *McKinney v. Revlon, Inc.*, 3 Cal. Rptr. 2d 72, 73, 75-76 (Ct. App. 1992) (affirming "trial court's imposition of liability for appellant's inadequate warning of known dangers" where plaintiff "filed a products liability complaint against Revlon alleging negligence and strict liability theories"); see also *infra* Section III.B (discussing litigation related to talcum body powders).

¹⁵⁹ See WILLIAM FUNK, SIDNEY SHAPIRO, DAVID VLADEK & KAREN SOKOL, *THE TRUTH ABOUT TORTS: USING AGENCY PREEMPTION TO UNDERCUT CONSUMER HEALTH AND SAFETY* 11 (2007); see also WILLIAM BUZBEE, WILLIAM FUNK, THOMAS MCGARITY, NINA MENDELSON, SIDNEY SHAPIRO, DAVID VLADEK & MATTHEW SHUDTZ, *THE TRUTH ABOUT TORTS: RETHINKING REGULATORY PREEMPTION AND ITS IMPACT ON PUBLIC HEALTH* 3-4 (2009).

cosmetics than men.¹⁶⁰ Cosmetics, both as products and an industry, are highly gendered.¹⁶¹ For example, “[o]n average, women use more cosmetics than men.”¹⁶² Women are significantly more likely than men to have jobs that may involve cosmetic exposure, such as hairdressers, hairstylists, and cosmetologists, and to be employed in beauty salons, nail salons, and other personal care services.¹⁶³ In addition, cosmetic advertisements often specifically target women.¹⁶⁴

Data on cosmetic injuries are limited. Current law does not require the submission of adverse event reports for cosmetics.¹⁶⁵ The director of FDA’s Office of Cosmetics and Colors has indicated that “[n]ot having mandatory reporting of adverse events by manufacturers often means that [FDA is] just seeing the tip of the iceberg in” the Center for Food Safety and Applied Nutrition’s Adverse Event Reporting System (“CAERS”) for cosmetics.¹⁶⁶ The submission of an adverse event report does not necessarily mean that a cosmetic caused the event.¹⁶⁷ Nevertheless, adverse event reports “are important because it’s one of the few tools FDA has to monitor possible safety problems with cosmetics.”¹⁶⁸ The consumers reported as experiencing adverse events in CAERS are 92% female, according to a slide deck from a 2017 presentation by the Director of FDA’s Office of Cosmetics and Colors.¹⁶⁹

¹⁶⁰ See Boyd, *supra* note 6, at 289-95; Anita Bernstein, *Fellow-Feeling and Gender in the Law of Personal Injury*, 18 J.L. & POL’Y 295, 302 (2009) (“Other female plaintiffs fall in a disparate impact category: women happened to encounter a particular dangerous product much more than men.”).

¹⁶¹ Boyd, *supra* note 6, at 289.

¹⁶² See *id.* at 289-90; *supra* notes 31-33 and accompanying text.

¹⁶³ Boyd, *supra* note 6, at 290-91.

¹⁶⁴ See HELEN RINGROW, *THE LANGUAGE OF COSMETICS ADVERTISING 2* (2016) (“The majority of cosmetics are marketed using the message that the female appearance can be improved with the aid of products . . .”).

¹⁶⁵ *Using Adverse Event Reports*, *supra* note 10.

¹⁶⁶ *Id.*

¹⁶⁷ See, e.g., LINDA M. KATZ, *COSMETIC ADVERSE EVENT REPORTING IN THE U.S.* 8 (2017) [hereinafter KATZ, *COSMETIC ADVERSE EVENT REPORTING*], <http://eservices.personalcarecouncil.org/science/17ss/presentations/katz.pdf> [<https://perma.cc/4RCL-YG7S>] (explaining limitations of CAERS data); *FDA Begins Posting Adverse Event Report Data for Foods and Cosmetics*, U.S. FDA (Dec. 7, 2017), <https://www.fda.gov/food/cfsan-constituent-updates/fda-begins-posting-adverse-event-report-data-foods-and-cosmetics> [<https://perma.cc/HP77-48BU>] (stating that FDA “has not necessarily determined if the product(s) in question were the actual cause of the events reported”); see also Saya L. Jacob, Erika Cornell, Michael Kwa, William E. Funk & Shuai Xu, Commentaries, *Cosmetics and Cancer: Adverse Event Reports Submitted to the Food and Drug Administration*, 2 J. NAT’L CANCER INST. 1, 2 (2018) (discussing limitations of reporting).

¹⁶⁸ *Using Adverse Event Reports*, *supra* note 10.

¹⁶⁹ KATZ, *COSMETIC ADVERSE EVENT REPORTING*, *supra* note 167, at 12.

That women may be disproportionately at risk of injury from cosmetics is consistent with Thomas Koenig and Michael Rustad's argument that "[s]pecific injuries vary significantly by sex" and there are "his and her" torts.¹⁷⁰ They note that "[t]he product injuries sustained by women plaintiffs in punitive damages cases occurred in traditionally female spheres."¹⁷¹ They indicate that compared to men, women are more likely to be injured by beauty products.¹⁷² They also note that "household products" injuries occurred "in gender stereotypical ways."¹⁷³ Two of the three examples they provide of "[f]emales [who] were awarded punitive damages for having been injured at home" involve cosmetics—"a skin cream containing mercury"¹⁷⁴ and an "artificial fingernail glue."¹⁷⁵

The preemption of cosmetic claims may also have a disparate impact on women who are members of other historically excluded groups who may be at an even higher risk of having adverse effects from cosmetics. Spending data suggests that Black women buy and use more cosmetics than the general population.¹⁷⁶ In addition, "there also may be racial differences in the types of cosmetics women use" and how they use them.¹⁷⁷ For example, "African American and African Caribbean women are more likely [than White women] to use a greater number and variety of hair products and to have their hair chemically or professionally treated."¹⁷⁸

Manufacturers may engage in racially targeted advertising of products that may have health implications for people of color.¹⁷⁹ Advertising, product use,

¹⁷⁰ Thomas Koenig & Michael Rustad, *His and Her Tort Reform: Gender Injustice in Disguise*, 70 WASH. L. REV. 1, 33 (1995); see also Bernstein, *supra* note 160, at 301 ("[G]ender in the United States has been especially central to the phenomenon of claiming and receiving compensation for injuries ascribed to defective products.").

¹⁷¹ Koenig & Rustad, *supra* note 170, at 38.

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ *Id.* at 38 n.146 (citing *Dean v. Mitchum-Thayer, Inc.*, 450 F. Supp. 1, 3 (E.D. Tenn. 1978)); see *Dean*, 450 F. Supp. at 3 (granting defendant's motion for a new trial on the issue of damages).

¹⁷⁵ Koenig & Rustad, *supra* note 170, at 38 n.146 (citing *Kicklighter v. Nails by Jannee, Inc.*, 616 F.2d 734, 745 (5th Cir. 1980)); see *Kicklighter*, 616 F.2d at 745 (reversing the judgment against the third-party defendant, a supplier of the defendant, and the defendant; remanding for a new trial; and affirming the judgment notwithstanding the verdict in favor of the defendant on punitive damages).

¹⁷⁶ Boyd, *supra* note 6, at 291 & nn.97-99 (discussing and citing works on differences in the use of and exposure to cosmetics).

¹⁷⁷ *Id.* at 291 & nn.100-02, 294 & nn.124-27.

¹⁷⁸ Zota & Shamasunder, *supra* note 34, at 419.

¹⁷⁹ Ross D. Petty, Anne-Marie G. Harris, Toni Broaddus & William M. Boyd III, *Regulating Target Marketing and Other Race-Based Advertising Practices*, 8 MICH. J. RACE & L. 335, 349 (2003) (examining targeted marketing techniques and how "race-based advertising practices can create negative results when harmful products, such as cigarettes or

and race are often intertwined, and the cosmetic industry has a long history of reinforcing “white-centred beauty ideals.”¹⁸⁰ One author described the relationship between Black women and the cosmetic industry as “complicated . . . symbolis[ing] equality and increased representation, but also manipulation and exploitation.”¹⁸¹

Employment in jobs that involve the use of cosmetics may also vary by race.¹⁸² For example, according to United States Bureau of Labor Statistics data cited earlier, in 2020, 79.3% of manicurists and pedicurists were women and 76.7% were Asian, whereas only 14.2% were White.¹⁸³ In comparison, 90.8% of hairdressers, hairstylists, and cosmetologists were women, and 77.5% were White, whereas only 5.1% were Asian.¹⁸⁴ In addition, “[t]he cosmetics that women who are members of other excluded groups are exposed to . . . may be more hazardous.”¹⁸⁵ For example, an analysis by the EWG found that “[f]ewer than one-fourth of the products marketed to Black women scored low in potentially hazardous ingredients, compared to about 40 percent of the items in [EWG’s cosmetic database] marketed to the general public.”¹⁸⁶

B. *How Tort Law May Complement & Reinforce the Regulation of Cosmetics*

Tort law may play several important roles in complementing the regulatory system for cosmetics.¹⁸⁷ If a defective or unreasonably dangerous cosmetic injures someone, the tort system provides a mechanism by which that person may seek compensation for their injury. The tort system also may incentivize cosmetic manufacturers to take due care or otherwise change their activities to reduce potential harms.

alcohol, are marketed more heavily toward minority consumers than toward the general population”); *see also* Zota & Shamasunder, *supra* note 34, at 419 (discussing “disproportionate beauty product exposures among vulnerable populations” and citing various studies).

¹⁸⁰ Melissa L. Baird, *‘Making Black More Beautiful’: Black Women and the Cosmetics Industry in the Post-Civil Rights Era*, 33 *GENDER & HIST.* 557, 562 (2021). *See generally* Imani Perry, *Buying White Beauty*, 12 *CARDOZO J.L. & GENDER* 579, 587 (2006) (discussing white-centric beauty standards, skin-bleaching, and history of “colonialism, neocolonialism, and most recently, economic globalization,” shaping beauty standards).

¹⁸¹ Baird, *supra* note 180, at 571.

¹⁸² Boyd, *supra* note 6, at 292 & nn.103-04.

¹⁸³ *Labor Force Statistics*, *supra* note 33.

¹⁸⁴ *Id.*

¹⁸⁵ Boyd, *supra* note 6, at 294 & nn.124-127; *see also* Helm et al., *supra* note 35, at 456 (“Given the exposure and endocrine-mediated health disparities experienced by Black women, new research and regulatory activities should consider the effects of ethnic differences in product use on exposures and health.”).

¹⁸⁶ *Big Market for Black Cosmetics*, *supra* note 35.

¹⁸⁷ *See* Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44 *S.C. L. REV.* 187, 251 (1993) (“Both federal product safety legislation and state products liability doctrines promote public health and safety, though in different ways.”).

1. Providing Redress

First, given cosmetics' gendered and racialized nature, tort law—"a law for the redress of wrongs"—may serve a particularly important function.¹⁸⁸ The FDCA gives FDA the authority to regulate cosmetics, but it confers no private right of action.¹⁸⁹ Tort law, in contrast, empowers people to demand a response for a wrong they have suffered.¹⁹⁰ In doing so, it "affirms their status as persons who are entitled not to be mistreated by others" in a way that "[e]x ante safety regulations" may not.¹⁹¹ "As a forum that is in principle available to anyone who has been victimized in a certain way," tort law may show people that "the government has a certain level of concern for their lives, liberties, and prospects."¹⁹² This function may be especially important in the cosmetic context because the inadequacies of the current regulatory scheme send the opposite message: one of the reasons cosmetics are underregulated is that they "are closely associated with femininity, [and] traits and qualities associated with women or femininity have been devalued."¹⁹³ In addition, the potentially empowering aspects of tort law may be particularly important in the cosmetic context because the people injured may be more likely to be women, including women who are members of other historically excluded groups, and there is a long history of discrimination against these groups—including by the federal and state governments.¹⁹⁴ The preemption of state tort law claims for defective or unreasonably dangerous cosmetics would have the practical effect of preventing people—disproportionately women, including women who are members of other historically excluded groups—injured by such cosmetics from obtaining redress through the tort law system.

¹⁸⁸ See generally John C.P. Goldberg, *The Constitutional Status of Tort Law: Due Process and the Right to a Law for the Redress of Wrongs*, 115 YALE L.J. 524 (2005).

¹⁸⁹ Federal Food, Drug, and Cosmetic Act (FDCA) § 310, 21 U.S.C. § 337 (providing that, except as specified in Section 337(b), "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States" and providing no explicit private right of action); see, e.g., Beck & Valentine, *supra* note 39, at 402 & n.96 (asserting that "court decisions over the last two decades have unanimously precluded private actions for alleged FDCA violations when styled as private rights of action" and citing decisions to support the assertion).

¹⁹⁰ Goldberg, *supra* note 188, at 601-07.

¹⁹¹ *Id.* at 607.

¹⁹² *Id.* But see *infra* Section II.C.2 (discussing gender and racial injustice throughout tort law).

¹⁹³ Boyd, *supra* note 6, at 318; see also Martha Chamallas, *The Architecture of Bias: Deep Structures in Tort Law*, 146 U. PA. L. REV. 463, 474-80 (1998) (discussing how women and their activities have been devalued); Mary Anne C. Case, *Disaggregating Gender from Sex and Sexual Orientation: The Effeminate Man in the Law and Feminist Jurisprudence*, 105 YALE L.J. 1, 3 (1995).

¹⁹⁴ See Boyd, *supra* note 6, at 275.

2. Compensating Injured People

Second, the preemption of state tort law claims for defective or unreasonably dangerous cosmetics also would eliminate the possibility that people—again disproportionately women, including women who are members of other historically excluded groups—injured by a defective or unreasonably dangerous cosmetic could receive compensation for their loss or injury through the tort system in the form of damages. Tort damages aim to compensate the plaintiff for their loss or injury and put them back into the position they were in before the injury occurred (i.e., to “make-whole”) to the extent possible with money.¹⁹⁵ Indeed, “[c]ompensation of persons injured by wrongdoing is one of the generally accepted aims of tort law.”¹⁹⁶ And, as discussed in more detail in Section II.C.2 below, even the imperfect compensatory function of tort law is likely better for injured persons than no compensation at all. Partial and imperfect compensation help to shift at least part of the loss off the injured person.¹⁹⁷

While the preemption landscape for products regulated by FDA is complex, state tort law has not been preempted and continues to provide a potential remedy for people injured by some products regulated by FDA, even where such products are subject to more stringent regulation than cosmetics. For example,

¹⁹⁵ See, e.g., Andrew Jay McClurg, *It's a Wonderful Life: The Case for Hedonic Damages in Wrongful Death Cases*, 66 NOTRE DAME L. REV. 57, 66 (1990) (“This compensatory function of tort law finds more specific expression in the ‘make whole’ principle, according to which the object of tort damages is to restore the tort victim as nearly as possible to the position he would have been in had the injury not occurred.”); Pam A. Mueller, *Victimhood & Agency: How Taking Charge Takes Its Toll*, 44 PEPP. L. REV. 691, 694-95 (2017) (stating that an “important goal of the civil justice system—particularly within tort law . . . is to make this victim whole” and that “[g]enerally, making a victim whole means compensating him financially to the extent necessary to return him to his previous position or as near as possible” (citations omitted)); see also Barbara Young Welke, *The Cowboy Suit Tragedy: Spreading Risk, Owning Hazard in the Modern American Consumer Economy*, 101 J. AM. HIST. 97, 100 (2014) (“[T]he burden of owning hazard in the goods of everyday life rests where it first materializes on the bodies and lives of individuals.”).

¹⁹⁶ DOBBS ET AL., *supra* note 41, § 2.4, at 21.

¹⁹⁷ From a loss-spreading standpoint, tort law may be beneficial in that it may help to shift (some of) the loss off the person injured by the defective or unreasonably dangerous cosmetic and spread the loss across many. Ronen Avraham & Kimberly Yuracko, *Torts and Discrimination*, 78 OHIO ST. L.J. 661, 693 (2017) (discussing the loss-spreading theory of distributive justice in tort law). This may be beneficial “because small, predictable losses [may] hurt less than abrupt losses that are considerable and unpredictable.” *Id.* This may, however, have negative secondary accident costs because the people to whom these costs may shift—other users of cosmetics—may be more likely to be women, including women who are members of other historically excluded groups. *Id.* However, a well-functioning regulatory structure may help to address this problem by using information obtained from the tort law system about product risks to better tailor regulation to the risks and ultimately reduce injuries and the costs of such injuries. See *id.*

drugs, which FDA regulates far more stringently than cosmetics,¹⁹⁸ are not subject to an express preemption provision, and the Supreme Court has held that failure-to-warn claims against the manufacturer of a (brand-name) prescription drug are not preempted.¹⁹⁹ As a result, someone injured by such a drug in a way that the drug failed to warn about may bring a state tort law claim against the manufacturer.²⁰⁰

In contrast to the tort system, a central aim of which is compensation,²⁰¹ the regulatory system for cosmetics does not provide compensation to people injured by defective or unreasonably dangerous cosmetics.²⁰² Moreover, while Congress could enact an alternative compensation system for cosmetics as part of cosmetic reform, it is unlikely to do so. None of the recent cosmetic bills would have established such a system.²⁰³ Although Congress has established alternate compensation systems in other contexts, those contexts can be distinguished from cosmetics. For example, in the food and drug context, Congress has established a compensation program for people injured by vaccines, an important public health tool.²⁰⁴ It has also established measures to

¹⁹⁸ A drug, for example, must have FDA approval before it may be marketed in the United States. *See* Federal Food, Drug, and Cosmetic Act (FDCA) § 505(a), 21 U.S.C. § 355(a).

¹⁹⁹ *See* *Wyeth v. Levine*, 555 U.S. 555, 574 (2009) (noting that Congress has not enacted an express preemption clause for prescription drugs).

²⁰⁰ *See id.* In contrast, the Supreme Court has held that state failure-to-warn claims and certain state law design-defect claims involving generic drugs are preempted. *See* *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 608-09 (2011). Some state claims involving medical devices are preempted under the Medical Device Amendments preemption clause. FDCA § 521(a), 21 U.S.C. § 360k(a); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (holding that certain state claims are preempted under the Medical Device Amendments preemption clause).

²⁰¹ *See supra* notes 196-97 and accompanying text.

²⁰² The FDCA does not provide a private right of action. *See* FDCA § 310, 21 U.S.C. § 337.

²⁰³ *See* Personal Care Products Safety Act, S. 2100, 117th Cong. (2021); Cosmetic Safety Enhancement Act of 2019, H.R. 5279, 116th Cong. (2019); Safe Cosmetics and Personal Care Products Act of 2019, H.R. 4296, 116th Cong. (2019); Personal Care Products Safety Act, S. 726, 116th Cong. (2019); FDA Cosmetic Safety and Modernization Act, S. 2003, 115th Cong. (2017); Cosmetic Modernization Amendments of 2017, H.R. 575, 115th Cong. (2017).

²⁰⁴ *See About the National Vaccine Injury Compensation Program*, HEALTH RES. & SERVS. ADMIN. (Jan. 2022) [hereinafter *About VICP*], <https://www.hrsa.gov/vaccine-compensation/about/index.html> [https://perma.cc/R9XD-F7N9]. The National Childhood Vaccine Injury Compensation Program (“VICP”), created by the National Childhood Vaccine Injury Act of 1986 (the “Vaccine Act”), is a “no-fault” compensation system for vaccine injuries, funded by an excise tax on vaccines. *Id.*; *see* National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-1 to -34). Vaccines have been recognized as “one of the greatest achievements of biomedical science and public health.” *See* CDC, *Ten Great Public Health Achievements—United States, 1900-1999*, 48 MORBIDITY & MORTALITY WKLY. REP. 241, 247 (1999). Routine childhood vaccination in the United States is estimated to prevent “322 million illnesses, 21 million

compensate people injured by covered countermeasures—items used to prevent, diagnose, or treat a public health emergency or a security threat—such as vaccines, medications, and devices.²⁰⁵ There is nothing to suggest that Congress

hospitalizations, and 732,000 deaths” among children born between 1994-2013 during their lifetimes. Cynthia G. Whitney, Fangjun Zhou, James Singleton & Anne Schuchat, *Benefits from Immunization During the Vaccines for Children Program Era—United States, 1994-2013*, 63 MORBIDITY & MORTALITY WKLY. REP. 352, 352 (2014). The benefits of vaccines are not limited to reducing the rate of disease and the asymptomatic carrier state. C. Lee Ventola, *Immunization in the United States: Recommendations, Barriers, and Measures to Improve Compliance, Part 1: Childhood Vaccinations*, 41 PHARM. & THERAPEUTICS 426, 426 (2016). When enough people are vaccinated, unvaccinated people also benefit from a “reduced risk of exposure to pathogens” (i.e., “herd immunity”). *Id.* Despite these substantial benefits, “[i]n very rare cases, a vaccine can cause a serious problem.” *Overview, History, and How the Safety Process Works*, CDC (Sept. 9, 2020), <https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html#four> [<https://perma.cc/QGA5-NBR8>].

Prior to enacting the Vaccine Act, Congress was concerned that, without intervention, vaccine manufacturers would leave the market because of potential liability and product liability insurance costs, thereby creating a shortage of vaccines. H.R. REP. NO. 99-908, at 7 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6348. There were only one or two manufacturers of several childhood vaccines, and a House Report on the legislation indicates that “[t]he loss of any of the existing manufacturers of childhood vaccines . . . could create a genuine public health hazard.” *Id.* Congress enacted the VICP to “ensure an adequate supply of vaccines,” “stabilize vaccine costs,” and “establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines.” *About VICP, supra*.

²⁰⁵ 42 U.S.C. § 247d-6d; *see also* Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17 2020) (addressing COVID-19 public health emergency); HEALTH RES. & SERVS. ADMIN., COUNTERMEASURES INJURY COMPENSATION PROGRAM (2020), <https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicpfactsheet.pdf> [<https://perma.cc/FR3C-YK8X>]; *Countermeasures Injury Compensation Program (CICP)*, HEALTH RES. & SERVS. ADMIN. (Nov. 2020), <https://www.hrsa.gov/cicp> [<https://perma.cc/5JLK-EJR6>]. While a comprehensive review of alternate compensation programs is beyond the scope of this Article, there are a variety of other compensation programs, which include, for example, those related to government activities (e.g., nuclear weapon development), specific events (e.g., September 11th attacks), and occupational disease (e.g., black lung disease). *See, e.g., Program Benefits*, U.S. DEP’T OF LAB., <https://www.dol.gov/agencies/owcp/energy/regs/compliance/progbenefits> [<https://perma.cc/3E95-XHZE>] (last visited Feb. 10, 2022) (describing the Energy Employees Occupational Illness Compensation Program); *Radiation Exposure Compensation Act*, U.S. DOJ, <https://www.justice.gov/civil/common/reca> [<https://perma.cc/XU79-2Z8Y>] (last visited Jan. 17, 2022) (describing the “administrative program for claims relating to atmospheric nuclear testing and uranium industry employment”); SEPT. 11TH VICTIM COMP. FUND, <https://www.vcf.gov/> [<https://perma.cc/XHG9-CLLF>] (last visited Jan. 17, 2022) (describing the September 11th Victim Compensation Fund); *Black Lung Program*, U.S. DOJ, <https://www.dol.gov/agencies/owcp/dcmwc> [<https://perma.cc/CH9S-ZQZ9>] (last visited Feb. 10, 2022) (stating that Black Lung Benefits Act “provides compensation to coal miners who are totally disabled by pneumoconiosis arising out of coal mine employment, and to survivors of coal miners whose deaths are attributable to the disease” and “provides eligible miners with medical coverage for the treatment of lung diseases related to pneumoconiosis”).

would find an alternative compensation system for cosmetics warranted. Thus, if cosmetic claims were preempted, people, disproportionately women, including members of other excluded groups, injured by cosmetics may be left without compensation for their injuries,²⁰⁶ which raises equity concerns. More broadly, if the claims involving female-gendered products are more likely to be preempted than similar claims that involve products that are more likely to injure men, this is concerning.

3. Encouraging Due Care & More

Third, tort litigation may have “radiating effects.”²⁰⁷ For example, tort law aims “to deter certain kinds of conduct by imposing liability when that conduct causes harm.”²⁰⁸ Thus tort law may encourage those who make, sell, and distribute cosmetics to take due care to avoid potential tort liability.²⁰⁹ This function may help make cosmetics safer by providing feedback to cosmetic industry members that they should take greater safety precautions to avoid such liability. In this way, tort law may complement and help reinforce the regulatory system. And while tort law may under deter in the cosmetic context, because of gender and racial bias and discrimination,²¹⁰ any deterrent effect is likely better than none—the result if tort law claims were preempted.

Deterrence is not the only way in which the possibility of tort liability may influence behavior. Tort litigation and the normative messages it conveys can “have broader social significance.”²¹¹ For example, in *The Radiating Effects of Torts*, Anne Bloom considers the radiating effect of tobacco litigation in altering public perceptions, “refram[ing] policy debates and contribut[ing] to the formation of new social norms.”²¹² Bloom states that “[u]ltimately, the

²⁰⁶ Worker’s compensation may cover some cosmetics-related injuries. See *Babcock-Bucklin v. Workers’ Comp. Appeals Bd.*, 202 Cal. Rptr. 670, 670, 672, 674 (Ct. App. 1984) (discussing hairstylist’s workers’ compensation claim after exposure to chemicals used in beauty shop where she worked); *Ocean Reef Club, Inc. v. Wilczewski*, 99 So. 3d 1, 2 (Fla. Dist. Ct. App. 2012) (discussing workers’ compensation in the context of a tort action brought by plaintiffs employed as a hairstylist and nail technician who alleged “to have been exposed to chemical fumes inherent in the operation of the beauty salon which caused them to experience [injuries] . . . for which they had to receive medical treatment and hospitalization”). But see Amanda A. Lee, Maia Ingram, Carolina Quijada, Andres Yubeta, Imelda Cortez, Nathan Lothrop & Paloma Beamer, *Responsibility for Chemical Exposures: Perspectives from Small Beauty Salons and Auto Shops in Southern Metropolitan Tucson*, 21 BMC PUB. HEALTH 271, 272 (2021) (noting that many Latinx workers in the beauty industry “do not understand or are not offered workers’ compensation benefits in cases of workplace injuries” such as exposure to toxic agents).

²⁰⁷ Anne Bloom, *The Radiating Effects of Torts*, 62 DEPAUL L. REV. 229, 233 (2013).

²⁰⁸ DOBBS ET AL., *supra* note 41, § 2.5, at 23.

²⁰⁹ See *id.* (stating that the “idea of deterrence” is that “all persons, recognizing potential tort liability, would tend to avoid conduct such that could lead to tort liability”).

²¹⁰ See *infra* Section II.C.2.

²¹¹ Bloom, *supra* note 207, at 233.

²¹² *Id.* at 240.

normative messages generated by the litigation proved helpful in resetting the policy agenda.”²¹³ And, perhaps more relevant for the cosmetic industry, given the recent allegations that some talc products contained asbestos, Bloom writes that “asbestos litigation seems to have altered the balance of power in the asbestos policymaking setting.”²¹⁴ In the cosmetic context, tort litigation could have a similar effect. It may change how people view the industry, what they expect from regulation, and how they value and use cosmetics.²¹⁵ And in so doing, it may reframe the policy debates over cosmetic regulation and help pave the way for meaningful reform.

In addition, Bloom considers how tort law can impact social hierarchies—either restructuring identities and social hierarchies or reproducing them.²¹⁶ As noted earlier, being able to invoke claims for injuries may empower those who have been injured and “shape[] identity and perceptions of political opportunity.”²¹⁷ In light of this, preempting state tort law claims in the cosmetic context may send a message of invisibility, exclusion, and powerlessness to people harmed by cosmetics.²¹⁸ This outcome may be particularly destructive given that these people may be disproportionately women and women who are members of other historically excluded groups.

4. Facilitating Information Access

One of the classic justifications for administrative agencies is that Congress delegates power to agencies because agencies’ expertise and specialized knowledge make them better suited to make certain types of decisions.²¹⁹ Many proponents of broad federal preemption of state tort law actions argue that agencies—and not lay juries—should decide how product risks and benefits are weighed because of their expertise, particularly in the health and safety

²¹³ *Id.*; see also Lynn Mather, *Theorizing About Trial Courts: Lawyers, Policymaking, and Tobacco Litigation*, 23 LAW & SOC. INQUIRY 897, 897, 936 (1998).

²¹⁴ Bloom, *supra* note 207, at 240; see also Lisa Girion, *Johnson & Johnson Knew for Decades that Asbestos Lurked in its Baby Powder*, REUTERS (Dec. 14, 2018, 2:00 PM), <https://www.reuters.com/investigates/special-report/johnsonandjohnson-cancer/> [<https://perma.cc/8XF5-B7DV>].

²¹⁵ See Bloom, *supra* note 207, at 234.

²¹⁶ *Id.* at 232-37.

²¹⁷ *Id.* at 237. *But see id.* at 245 (“The radiating effects of torts also likely help to enforce and construct social hierarchies along the lines of gender and race.”).

²¹⁸ *Id.* at 237; see also PATRICIA J. WILLIAMS, *THE ALCHEMY OF RACE AND RIGHTS* 164 (1991) (describing rights as “the magic wand of visibility and invisibility, of inclusion and exclusion, of power and no power”).

²¹⁹ See Barry Sullivan & Christine Kexel Chabot, *The Science of Administrative Change*, 52 CONN. L. REV. 1, 27 (2020) (discussing the history of expertise as a justification for agency authority). This advantage, however, might not be as great as “an abstract comparison of the nature of [experts and civil juries] might suggest.” FUNK ET AL., *supra* note 159, at 15.

context.²²⁰ However, the idea of an expert decision-maker is premised on the notion that that decision-maker will have access to information to make a determination.²²¹ Taken to an extreme, if no information is available, the agency has nothing on which to base its decision. As Mary J. Davis has argued, “common law tort doctrines *should* continue to play a role in the regulatory framework” because there “is [a] need for an alternative, complementary mechanism to the typically static administrative regulatory framework to encourage the disclosure of, and promote responses to, constantly evolving risk information.”²²²

FDA is “undoubtedly an expert agency.”²²³ Its mission is to protect and promote the public health.²²⁴ Specifically, “[FDA] is responsible for protecting the public health by ensuring . . . the safety of . . . cosmetics.”²²⁵ But under current law, FDA’s ability to collect even basic information about cosmetics and their risks is limited.²²⁶ As noted above, FDA does not have the authority to mandate establishment or product registration, require adverse event reporting, or generally inspect records.²²⁷ For example, FDA noted that in the course of inspecting facilities for certain cosmetic products, it “learned that consumers had reported reactions in more than 21,000 complaints submitted to . . . the companies that market and manufacture the products.”²²⁸ However, “[t]he law does not require cosmetic companies to share their safety information, including consumer complaints, with the FDA, nor does the law require mandatory reporting of adverse events to the FDA.”²²⁹ And even if Congress were to give

²²⁰ See Mary J. Davis, *The Case Against Preemption: Vaccines & Uncertainty*, 8 IND. HEALTH L. REV. 293, 293 (2011).

²²¹ See, e.g., 5 U.S.C. § 553(c) (“After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose.”); *Id.* § 554(a) (“This section applies . . . in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing”); Sullivan & Chabot, *supra* note 219, at 6 (“Expert decisions often turn, not on the mastery of static bodies of information, but on the assessment of evolving scientific, technological, or economic knowledge.”).

²²² Davis, *supra* note 220, at 294. *But see* Sullivan & Chabot, *supra* note 219, at 6 (“[A]dministrative agencies, amongst all government decisionmakers, are uniquely situated to incorporate evolving scientific, technological, or economic information into sound regulatory decisions”).

²²³ K.M. Lewis, *Informal Guidance and the FDA*, 66 FOOD & DRUG L.J. 507, 535 (2011).

²²⁴ See Federal Food, Drug, and Cosmetic Act (FDCA) § 1003, 21 U.S.C. § 393; *What We Do*, U.S. FDA (Mar. 28, 2018), <https://www.fda.gov/about-fda/what-we-do> [<https://perma.cc/W6AA-WN4D>].

²²⁵ *What We Do*, *supra* note 224.

²²⁶ See, e.g., *Information for Consumers About WEN*, *supra* note 4 (“The law does not require cosmetic companies to share their safety information, including consumer complaints, with the FDA, nor does the law require mandatory reporting of adverse events to the FDA.”).

²²⁷ See *supra* notes 74-79 and accompanying text.

²²⁸ *Information for Consumers About WEN*, *supra* note 4.

²²⁹ *Id.*

FDA the authority to collect this information, tort law can help bring to light additional information about the risks that cosmetics may pose and with which members of the cosmetic industry may not be forthcoming.²³⁰ Such information may come from the company making, distributing, or selling the regulated product in civil discovery in the context of tort litigation.²³¹ It may also come as a result of litigation publicity.²³²

C. *The Intersecting Failures of Cosmetic Regulation, Healthcare & Tort Law*

1. Disparities in Healthcare

Women, including women who are members of other excluded groups, are not only disproportionately put at risk by the inadequate regulation of cosmetics, but, if they are injured by a cosmetic and seek medical care, they do so within a medical and healthcare system in which there are significant gender-based disparities. For example, “[h]istorically, women have been excluded from or underrepresented in the drug development process, and in clinical research in particular.”²³³ For years, FDA’s guidelines “largely excluded women from clinical trials” for drugs.²³⁴ As a result, research was “conducted predominately with only white male participants and then the results of those studies were

²³⁰ See, e.g., FUNK ET AL., *supra* note 159, at 11 (discussing how “the federal regulatory system permits drug and medical-device manufacturers to evade safety requirements and maintain strict control of information on the health risks presented by their products” and stating that “[t]ort law is necessary . . . to highlight dangers that FDA misses or fails to address”); Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines*, 109 CALIF. L. REV. 493, 516 (2021) (“In the United States, a small but vital stream of safety and efficacy data on prescription drugs is unearthed via discovery in tort and other litigation.”); see also Adam D.K. Abelkop, *Tort Law as an Environmental Policy Instrument*, 92 OR. L. REV. 381, 445-51 (2013) (discussing the role of tort law in gathering information in the context of environmental regulation). For a discussion of information problems within FDA-regulated industries, see Richard A. Nagareda, *FDA Preemption: When Tort Law Meets the Administrative State*, 1 J. TORT L. 4, 43-45 (2006); and Jacqueline Fox, *Reinvigorating the Concept of Benefit: The Failure of Drug Company-Sponsored Research on Human Subjects*, 38 SETON HALL L. REV. 605, 607 (2008).

²³¹ See *infra* Section III.H.

²³² See *infra* Section III.H.

²³³ Cynthia Hathaway, *A Patent Extension Proposal to End the Underrepresentation of Women in Clinical Trials and Secure Meaningful Drug Guidance for Women*, 67 FOOD & DRUG L.J. 143, 144 (2012).

²³⁴ Karen H. Rothenberg, *Gender Matters: Implications for Clinical Research and Women’s Health Care*, 32 HOUS. L. REV. 1201, 1237 (1996); see also U.S. DEP’T OF HEALTH, EDUC., & WELFARE, GENERAL CONSIDERATIONS FOR THE CLINICAL EVALUATION OF DRUGS 10 (1977) (“In general, women of childbearing potential should be excluded from the earliest dose ranging studies.”).

extrapolated and applied to the remainder of the population.”²³⁵ While FDA has since changed its guidance, and the National Revitalization Act of 1993 now requires that the Director of the National Institutes of Health (“NIH”) ensure the participation of women and minority groups in NIH-funded research, disparities remain.²³⁶ A 2010 Institute of Medicine report states that “[a] lack of taking account of sex and gender differences in the design and analysis of studies, and a lack of reporting on sex and gender differences, has hindered identification of potentially important sex differences and slowed progress in women’s health research and its translation to clinical practice.”²³⁷ People of color have been, and continue to be, underrepresented in clinical trials.²³⁸ But gender bias is not limited to clinical research; it “extends . . . into all areas of health care: ‘it pervades medicine, beginning with medical-school admissions and education, encompassing research facilities and medical journals, and culminating in how women are treated as patients in clinics, hospitals, and physicians’ offices across the country[.]’”²³⁹ as does racial bias and discrimination.²⁴⁰ Many groups of color experience significant barriers to accessing care, receive lower-quality

²³⁵ Vicki Lawrence MacDougall, *Medical Gender Bias and Managed Care*, 27 OKLA. CITY U. L. REV. 781, 809 (2002) (examining the gender gap in medicine and discussing gender gaps in medical and scientific research).

²³⁶ See Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 58 Fed. Reg. 39406 (July 22, 1993); see also National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, sec. 131, § 429B(a)(1)(A), 107 Stat. 122, 133 (codified as amended at 42 U.S.C. § 289a-2); NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14508 (Mar. 28, 1994).

²³⁷ COMM. ON WOMEN’S HEALTH RSCH., BD. ON POPULATION HEALTH & PUB. HEALTH PRAC., INST. OF MED. OF THE NAT’L ACADS., WOMEN’S HEALTH RESEARCH: PROGRESS, PITFALLS, AND PROMISE 10 (2010).

²³⁸ See, e.g., SOC’Y FOR WOMEN’S HEALTH RSCH. & U.S. FOOD & DRUG ADMIN. OFF. OF WOMEN’S HEALTH, DIALOGUES ON DIVERSIFYING CLINICAL TRIALS: SUCCESSFUL STRATEGIES FOR ENGAGING WOMEN AND MINORITIES IN CLINICAL TRIALS i-ii (2011) [hereinafter DIVERSIFYING CLINICAL TRIALS], <https://www.fda.gov/media/84982/download> [<https://perma.cc/8SVM-QHES>]; Luther T. Clark, Laurence Watkins, Ileana L. Piña, Mary Elmer, Ola Akinboboye, Millicent Gorham, Brenda Jamerson, Cassandra McCullough, Christine Pierre, Adam B. Polis, Gary Puckrein & Jeanne M. Regnante, *Increasing Diversity in Clinical Trials: Overcoming Critical Barriers*, 44 CURRENT PROBS. CARDIOLOGY 148, 149 (2019); Isabell Yates, Jennifer Byrne, Susan Donahue, Linda McCarty & Allison Mathews, *Representation in Clinical Trials: A Review on Reaching Underrepresented Populations in Research*, 34 CLINICAL RESEARCHER 1, 4 (2020), <https://acrpnet.org/2020/08/10/representation-in-clinical-trials-a-review-on-reaching-underrepresented-populations-in-research/> [<https://perma.cc/9WWL-H69A>].

²³⁹ Rothenberg, *supra* note 234, at 1210 (quoting LESLIE LAURENCE & BETH WEINHOUSE, OUTRAGEOUS PRACTICES: THE ALARMING TRUTH ABOUT HOW MEDICINE MISTREATS WOMEN 5 (1994)).

²⁴⁰ See INST. OF MED. OF THE NAT’L ACADS., UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTHCARE 29-31 (Brian D. Smedley, Adrienne Y. Stith & Alan R. Nelson eds., 2003); Avraham & Yuracko, *supra* note 197, at 688 n.139 (citing literature on people of color receiving inferior healthcare treatment).

care, face greater risk of poor health outcomes, and suffer higher mortality than Whites.²⁴¹

Arguably, the limitations of the cosmetic regulatory system are more concerning when viewed against the backdrop of the medical and healthcare system, where gender and racial bias and discrimination may shape the care—or lack thereof—that injured women may receive. Women are disadvantaged as consumers by the inadequate regulation of cosmetics *and* as patients in the healthcare system. Removing the possibility of redress for injuries caused by cosmetics through the tort law system—as the preemption of state tort law in the cosmetic context would—arguably heightens this concern. However, tort law is not a panacea.

2. Gender & Racial Injustice & Tort Law

Like the regulatory system and the healthcare system, the tort law system—as part of the American judicial system—has been shaped by, and has helped perpetuate, bias and discrimination against women and members of other historically excluded groups. For example, while women and people of color are no longer barred from bringing lawsuits because of their race and gender,²⁴² certain groups may have a more difficult time accessing, and be less likely to access, the civil legal system than others. For example, “attorneys may be less likely to take the case of a woman or minority on a contingency fee basis because the potential recovery would be less.”²⁴³ “[A]ccess to the legal system, including

²⁴¹ DIVERSIFYING CLINICAL TRIALS, *supra* note 238, at ii; Pamela A. Meyer, Paula W. Yoon & Rachel B. Kaufmann, *Introduction: CDC Health Disparities & Inequalities Report—United States, 2013*, 62 MORBIDITY & MORTALITY WKLY. REP. (SUPP.) 3, 3 (2013); Ronald Wyatt, *Pain and Ethnicity*, 15 VIRTUAL MENTOR 449, 450 (2013); Samantha Artiga & Kendal Orgera, *Key Facts on Health and Health Care by Race and Ethnicity*, KAISER FAM. FOUND. (Nov. 12, 2019), <https://www.kff.org/report-section/key-facts-on-health-and-health-care-by-race-and-ethnicity-coverage-access-to-and-use-of-care/> [<https://perma.cc/M5K2-J298>]; Liz Hamel, Lunna Lopes, Cailey Muñana, Samantha Artiga & Mollyann Brodie, *KFF/The Undefeated Survey on Race and Health*, KAISER FAM. FOUND. (Oct. 13, 2020), <https://www.kff.org/report-section/kff-the-undefeated-survey-on-race-and-health-main-findings/#HealthCareSystem> [<https://perma.cc/7AFQ-2JC7>]; Nambi Ndugga & Samantha Artiga, *Disparities in Health and Health Care: 5 Key Questions and Answers*, KAISER FAM. FOUND. (May 11, 2021), <https://www.kff.org/racial-equity-and-health-policy/issue-brief/disparities-in-health-and-health-care-5-key-question-and-answers/> [<https://perma.cc/RE7A-TXGT>]; *Racial Equity and Health Data Dashboard*, KAISER FAM. FOUND., <https://www.kff.org/racial-equity-and-health-policy/dashboard/racial-equity-and-health-data-dashboard/> [<https://perma.cc/AAK2-UEBS>] (last visited Jan. 17, 2022).

²⁴² Chamallas, *supra* note 193, at 463-64.

²⁴³ Christian E. Schlegel, Comment, *Is a Federal Cap on Punitive Damages in Our Best Interest?: A Consideration of H.R. 956 in Light of Tennessee’s Experience*, 69 TENN. L. REV. 677, 698 (2002); see also Anita Bernstein, *Gender in Asbestos Law: Cui Bono? Cui Pacat?*, 88 TUL. L. REV. 1211, 1239 (2014); Catherine M. Sharkey, *Unintended Consequences of Medical Malpractice Damages Caps*, 80 N.Y.U. L. REV. 391, 489-90 (2005); Joanna M. Shepherd, *Tort Reforms’ Winners and Losers: The Competing Effects of Care and Activity*

the courts, continues to be a major obstacle for women of color”²⁴⁴—one of the groups that the inadequate regulation of cosmetics may disproportionately impact. Unequal access to the legal system may undermine the deterrent effect of tort law and create incentives for companies to take less care when it comes to groups that have less access to the legal system.

The types of injuries and damages associated with women and people of color have been devalued within tort law,²⁴⁵ just as cosmetics and their regulation may have been devalued and deprioritized due to cosmetics’ close association with femininity and women.²⁴⁶ When women and people of color do access the tort law system, they may receive smaller awards than White men²⁴⁷:

When it comes time for the calculation of awards, courts have embraced the use of work-life expectancy and wage tables constructed separately for men and women and for whites and blacks[, despite] the racial and gender disparities that result—including “discounting” awards in particular cases on account of a plaintiff’s race or gender—and the fact that the use of such tables reifies existing structural inequalities and historical patterns of participation in the workforce²⁴⁸

“Young female and minority tort victims”—the same people who may face the most risk because of the inadequate regulation of cosmetics—“bear the particular brunt of the effects of” this.²⁴⁹ In addition, tort reforms may have a

Levels, 55 UCLA L. REV. 905, 945 (2008) [hereinafter Shepherd, *Winners and Losers*] (stating that certain tort reforms will have disproportionate impact on women); Joanna Shepherd, *Uncovering the Silent Victims of the American Medical Liability System*, 67 VAND. L. REV. 151, 175 (2014) (“[T]ort reforms . . . disproportionately reduce contingent fee lawyers’ willingness to represent lower-income groups.”).

²⁴⁴ Jenny Rivera, *The Violence Against Women Act and the Construction of Multiple Consciousness in the Civil Rights and Feminist Movements*, 4 J.L. & POL’Y 463, 498 (1996); see also Sara Sternberg Greene, *Race, Class, and Access to Civil Justice*, 101 IOWA L. REV. 1263, 1268 (2016) (“[B]lack respondents . . . were less likely than white respondents to have sought, or considered seeking, legal help for their civil legal problems.”).

²⁴⁵ See generally Chamallas, *supra* note 193, at 464 (examining how “formal equality on the face of the law of torts bears little connection to gender and race equity as measured by real-world standards”).

²⁴⁶ Boyd, *supra* note 6, at 307.

²⁴⁷ See, e.g., Avraham & Yuracko, *supra* note 197, at 664 (stating that “the damages black women receive for future losses caused by bodily injury or wrongful death are lower than the damages their white male counterparts would receive”); see also Martha Chamallas, *Questioning the Use of Race-Specific and Gender-Specific Economic Data in Tort Litigation: A Constitutional Argument*, 63 FORDHAM L. REV. 73, 75 (1994) (examining gender and race bias in the calculation of damages in tort law).

²⁴⁸ Catherine M. Sharkey, *Valuing Black and Female Lives: A Proposal for Incorporating Agency VSL into Tort Damages*, 96 NOTRE DAME L. REV. 1479, 1485 (2021); see also Avraham & Yuracko, *supra* note 197, at 670, 673-77 (discussing how use of worklife expectancy and wage tables has “infused race and gender bias into damage calculations”).

²⁴⁹ Sharkey, *supra* note 248, at 1486.

disparate impact on women and people of color, further exacerbating existing disparities.²⁵⁰

D. *Why Both Federal Regulation & State Tort Law Are Needed*

The gender and race-related disparities in tort law and the healthcare system may intersect and reinforce each other in ways that are particularly detrimental to those who also disproportionately bear the risk of harm under the inadequate cosmetic regulatory system²⁵¹—a system that has lagged behind that of food, drugs, and medical devices, in part *because* cosmetics are a gendered product and industry.²⁵² For example, as discussed in Section II.A, the failures of the cosmetic regulatory system may disproportionately impact Black women who may be at higher risk of injury from cosmetics. 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 people’s injuries.”²⁵³ And if she then seeks redress for her injury through the tort

²⁵⁰ See, e.g., Joanne Doroshow & Amy Widman, *The Racial Implications of Tort Reform*, 25 WASH. U. J.L. & POL’Y 161, 161 (2007) (examining how “racial prejudice lurks behind the tort reform movement”); Lucinda M. Finley, *Female Trouble: The Implications of Tort Reform for Women*, 64 TENN. L. REV. 847, 865 (1997) (“Damage caps on medical malpractice recoveries will also fall most heavily on the gendered injury categories of sexual assault, reproductive harm, and *cosmetic injuries*.” (emphasis added)); Lucinda M. Finley, *The Hidden Victims of Tort Reform: Women, Children, and the Elderly*, 53 EMORY L.J. 1263, 1264-67 (2004) (noting the effects of damages caps); Koenig & Rustad, *supra* note 170, at 3-11 (highlighting falsity of gender-neutrality in tort law); Frank M. McClellan, *The Dark Side of Tort Reform: Searching for Racial Justice*, 48 RUTGERS L. REV. 761, 761 (1996) (noting that race matters when it comes to tort claims); Schlegel, *supra* note 243, at 697-98; Sharkey, *supra* note 243, at 490; Shepherd, *Winners and Losers*, *supra* note 243, at 945-60 (discussing disproportionate impacts of tort reforms on women and noting that “punitive damages typically have been awarded for injuries suffered almost exclusively by women”).

²⁵¹ For a discussion of how gender bias in the health care and judicial system may interact, see Cecilia Plaza, *Miss Diagnosis: Gendered Injustice in Medical Malpractice Law*, 39 COLUM. J. GENDER & L. 91, 139 (2020), which notes that it “adds to the current body of research by showing that there is a gendered injustice in both the medical and the legal fields and the gender imbalance in each field reinforces the other,” and also see MacDougall, *supra* note 235, at 787, which argues that “gender discrepancies in medical practices are more of a societal concern when the safety net of the judicial system is lacking.”

²⁵² Boyd, *supra* note 6, at 280, 318-19. Gender, however, cannot be separated from other factors such as race, ethnicity, sexual orientation, and socioeconomic status, which intersect with and shape women’s experiences. 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; Angela P. Harris, *Race and Essentialism in Feminist Legal Theory*, 42 STAN. L. REV. 581, 615 (1990).

²⁵³ Maytal Gilboa, *The Color of Pain: Racial Bias in Pain and Suffering Damages*, 56 GA. L. REV. (forthcoming 2021) (manuscript at 5), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3810779; see also Salimah H. Meghani, Eeeseung Byun &

system—a system that is plagued by disparities—she may receive a smaller award as a result of her race and gender.²⁵⁴ She may also be awarded lower pain and suffering damages as a result of her race and gender.²⁵⁵ The lower damages awards may create “incentives for defendants to direct risky and harmful conduct toward minority communities,” further exacerbating existing disparities.²⁵⁶

Despite these serious limitations, I contend that preempting tort law and removing it from this equation would make cosmetics less safe for everyone while also failing to alleviate—and perhaps even exacerbating—the disproportionate effects that the regulatory inadequacies may have on some groups. Tort law can help to strengthen and fill gaps in the regulatory system and vice versa. If state law cosmetic claims were preempted, the woman in the hypothetical above would be left without even the possibility of redress, recognition, or compensation that the tort system may provide, thus compounding the dignitary harms and perpetuating the financial ones. The regulatory system, while permitting public participation, does not provide the same possibilities, redress, and recognition as the tort system.²⁵⁷ As discussed earlier, the federal regulatory system provides no private right of action,²⁵⁸ and has not generally provided a mechanism to compensate injured people absent special circumstances.²⁵⁹ When a defective or unreasonably dangerous cosmetic injures a person, the losses should fall on those responsible for the products instead of remaining on a faultless injured consumer.

The preemption of cosmetic claims would remove even the possibility of tort liability, and with it, any future deterrent effect that it may provide. It also may reduce the availability of cosmetic safety information, which tort litigation, and specifically civil discovery, may reveal—information that could inform future regulatory actions and potentially help prevent future harms.²⁶⁰

Rollin M. Gallagher, *Time to Take Stock: A Meta-Analysis and Systemic Review of Analgesic Treatment Disparities for Pain in the United States*, 13 PAIN MED. 150, 170 (2012) (concluding, in a meta-analysis of twenty years of studies on racial and ethnic disparities in pain treatment, that “Blacks/African Americans . . . were at particularly greater risk for undertreatment” and that “[t]hese findings unequivocally point to the evidence that race and ethnicity matters in clinical pain treatment outcomes and the size of the difference is sufficiently large to warrant clinical safety and quality concerns”).

²⁵⁴ See *supra* Section II.C.2.

²⁵⁵ Gilboa, *supra* note 253 (manuscript at 6).

²⁵⁶ Sharkey, *supra* note 248, at 1489; see also Gilboa, *supra* note 253 (manuscript at 6).

²⁵⁷ In addition, the regulatory system may suffer from other limitations, including agency capture, limited authority, and insufficient funding. See, e.g., Elizabeth J. Cabraser, *Due Process Preempted: Stealth Preemption as a Consequence of Agency Capture*, 65 NYU ANN. SURV. AM. L. 449, 458 (2010); Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 CORNELL L. REV. 1003, 1020 (2008); *supra* Section I.C.1.b.

²⁵⁸ Federal Food, Drug, and Cosmetic Act (FDCA) § 310, 21 U.S.C. § 337.

²⁵⁹ See *supra* Section II.B.2.

²⁶⁰ See Abelkop, *supra* note 230, at 445-51 (discussing importance of tort law for information gathering in context of environmental regulation); *supra* Sections I.C.1.b, II.B.4.

At the same time, tort law is not a panacea. Its ability to protect and compensate women and people of color has significant limitations, which may undermine its ability to provide redress, recognition, and compensation. As a result of these limitations, manufacturers of unreasonably dangerous cosmetics may not be held accountable for the true cost of the injuries that their products cause, undermining the incentives for them to take due care. Moreover, while tort law may still have some (prospective) deterrent effect, it is still primarily focused on providing redress *after* an injury has occurred. As a result of these limitations, tort law does not eliminate the need for a well-functioning regulatory system.

III. THE COSMETIC-TALC LITIGATION: *INGHAM V. JOHNSON & JOHNSON*

Building on the discussion in the prior Part, this Part considers *Ingham v. Johnson & Johnson*, a recent case in which the plaintiffs alleged that cosmetic-talc body powders with asbestos caused their ovarian cancer. This Part situates its examination of *Ingham* within a broader discussion of FDA regulation, gender, race, and disparities in health, healthcare, and tort law and considers how preempting cases involving cosmetic claims may raise equity concerns.

At the outset, it is important to note that while *Ingham* has been decided, much of the litigation over cosmetic-talc products is ongoing, and there are important unresolved and disputed questions, including whether the products contained asbestos and whether the products can cause ovarian cancer as plaintiffs have alleged, as well as the ultimate issue of liability.²⁶¹ Nevertheless, this Part

²⁶¹ For a discussion of talc litigation, including litigation alleging talc products contained asbestos, see, for example, 4 LAWRENCE G. CETRULO, TOXIC TORTS LITIGATION GUIDE ch. 46, Westlaw (database updated Dec. 2020) and Joseph J. Welter & Jason A. Botticelli, *Cosmetic Talc Litigation: Two Emerging and Distinct Mass Torts*, TOXIC TORTS & ENV'T L. COMM. NEWSL., Summer 2017, at 7, 20. While this Article focuses on claims alleging that cosmetic-talc products caused ovarian cancer and the particular impacts on women, men have also made claims involving cosmetic-talc products. See, e.g., *McNeal v. Autozone Inc.*, No. BC698965 (Cal. Super. Ct. Mar. 20, 2018); see also Craig Clough, *LA Jury Hits Talc Supplier with \$4.8 Million Asbestos Verdict*, LAW360 (Apr. 19, 2021, 10:49 PM), <https://www.law360.com/articles/1376512/la-jury-hits-talc-supplier-with-4-8-million-asbestos-verdict> (discussing *McNeal* and stating that according to the firm representing the plaintiff, “Vietnam War veteran Willie McNeal Jr. suffers from pleural mesothelioma, a cancer of the lungs caused by asbestos exposure, and convinced the jury to link Whittaker [(a talc supplier)] to his diagnosis due to his 22-year daily use of Old Spice Talcum Powder”). In addition, it should be noted that in October 2021, Johnson & Johnson announced that its newly created subsidiary LTL Management LLC had filed for bankruptcy protection. 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/85AM-UWJG>]; see also Voluntary Petition for Non-Individuals Filing for Bankruptcy, *In re* LTL Mgmt. LLC, No. 21-30589 (Bankr. W.D.N.C. Oct. 14, 2021), *transferred*, No. 21-30589 (Bankr. D.N.J. Nov. 16, 2021). In a press release announcing that filing, Johnson & Johnson stated that the subsidiary “was established to hold and manage claims in the cosmetic talc litigation.” Press Release, Johnson & Johnson,

provides an examination of how many of the considerations discussed earlier may apply in the context of talc-containing cosmetics.

A. *Talc & Asbestos*

Talc is “a naturally occurring mineral” used in cosmetics.²⁶² It is used, for example, “to absorb moisture, to prevent caking, to make facial makeup opaque, or to improve the feel of a product.”²⁶³ There is the potential for talc to be contaminated with asbestos, another “naturally occurring silicate mineral” that “may be found in close proximity [to talc] in the earth.”²⁶⁴ Following reports of asbestos in talc-containing cosmetics, FDA sampled a number of talc-containing cosmetics and had them tested.²⁶⁵ In 2019, FDA announced that products from several different distributors and manufacturers tested positive for asbestos.²⁶⁶ The Interagency Working Group on Asbestos in Consumer Products (“IWGACP”) has indicated that talc is “the presumptive source of asbestos” in talc-containing cosmetics.²⁶⁷ However, questions about the possible contamination of talc with asbestos are not new. FDA notes that such questions “have been raised since the 1970s.”²⁶⁸

Asbestos is a known carcinogen when inhaled.²⁶⁹ FDA and other federal agencies have recognized “that there is no known safe level of asbestos

supra. When this Article was finalized, the bankruptcy case was pending. Voluntary Petition for Non-Individuals Filing for Bankruptcy, *In re LTL Mgmt. LLC*, No. 21-30589 (Bankr. W.D.N.C. Oct. 14, 2021), ECF No. 1, *transferred*, No. 21-30589 (Bankr. D.N.J. Nov. 16, 2021).

²⁶² See *Talc*, *supra* 100.

²⁶³ *Id.*

²⁶⁴ *Id.*

²⁶⁵ *Id.*

²⁶⁶ *FDA Summary of Results from Testing of Official Samples of Talc-Containing Cosmetics for Asbestiform Fibers by AMA Laboratories During FY19*, U.S. FDA [hereinafter *FDA Summary of Results*], <https://www.fda.gov/media/135911/download> [<https://perma.cc/26BA-JLH9>] (last visited Jan. 17, 2022).

²⁶⁷ See EXECUTIVE SUMMARY: PRELIMINARY RECOMMENDATIONS ON TESTING METHODS FOR ASBESTOS IN TALC AND CONSUMER PRODUCTS CONTAINING TALC 1 & n.1 (2020) [hereinafter EXECUTIVE SUMMARY], <https://www.fda.gov/media/134005/download> [<https://perma.cc/T6E9-7E72>] (“The recommendations and opinions expressed in this document are based on discussions on matters of ‘scientific debate’ (contentious issues that have not been completely resolved or finalized in the ongoing debate) among subject matter experts on the IWGACP and do not necessarily reflect the opinions or policies of their agencies.”).

²⁶⁸ *Talc*, *supra* note 100.

²⁶⁹ See, e.g., AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, PUB. HEALTH SERV., U.S. DEP’T OF HEALTH & HUM. SERVS., TOXICOLOGICAL PROFILE FOR ASBESTOS 7 (2001), <https://www.atsdr.cdc.gov/ToxProfiles/tp61.pdf> [<https://perma.cc/7U7D-XH7N>] (stating the Department of Health and Human Services, Environmental Protection Agency, and International Agency for Research on Cancer have all “determined that asbestos is carcinogenic to humans”).

exposure.”²⁷⁰ Asbestos exposure can cause asbestosis or pleural plaques and may cause cancers and mesothelioma.²⁷¹

The International Agency for Research on Cancer (“IARC”) Working Group on the Evaluation of Carcinogenic Risks to Humans has stated that there is a causal association between exposure to asbestos and ovarian cancer.²⁷² FDA, however, states that while “[p]ublished scientific literature going back to the 1960s has suggested a possible association between the use of powders containing talc in the genital area and the incidence of ovarian cancer[,] . . . these studies have not conclusively demonstrated such a link, or if such a link existed, what risk factors might be involved.”²⁷³

B. *Cosmetic-Talc Litigation*: Ingham v. Johnson & Johnson

In their 2020 annual reports, several companies indicated that they are facing a number of plaintiffs in products liability lawsuits related to talc body powders.²⁷⁴ Johnson & Johnson indicated that it was facing approximately

²⁷⁰ Press Release, U.S. FDA, FDA in Brief: FDA Releases Final Report of Talc-Containing Cosmetic Products Tested for Asbestos (Mar. 9, 2020), <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-releases-final-report-talc-containing-cosmetic-products-tested-asbestos> [<https://perma.cc/S4T3-G7EM>]; see also EXECUTIVE SUMMARY, *supra* note 267, at 1.

²⁷¹ See COMM. ON ASBESTOS: SELECTED HEALTH EFFECTS, BD. ON POPULATION HEALTH & PUB. HEALTH PRACS., INST. OF MED. OF THE NAT’L ACADS., ASBESTOS: SELECTED CANCERS 15-16, 81-82, 230-31 (2006); 100C INT’L AGENCY FOR RSCH. ON CANCER (IARC), WORLD HEALTH ORG., ARSENIC, METALS, FIBRES, AND DUSTS: A REVIEW OF HUMAN CARCINOGENS 233-41 (2012) [hereinafter MONOGRAPH 100C]; see also EXECUTIVE SUMMARY, *supra* note 267, at 1-2; *FDA Issues Update Regarding Information Presented at Talc Public Meeting*, U.S. FDA (Aug. 18, 2020), <https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-update-regarding-information-presented-talc-public-meeting> [<https://perma.cc/XT2H-TPHA>].

²⁷² See MONOGRAPH 100C, *supra* note 271, at 256 (“The Working Group noted that a causal association between exposure to asbestos and cancer of the ovary was clearly established . . .”).

²⁷³ *Talc*, *supra* note 100; see also 93 INT’L AGENCY FOR RSCH. ON CANCER (IARC), WORLD HEALTH ORG., IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS: CARBON BLACK, TITANIUM DIOXIDE AND TALC 412 (2010) [hereinafter WHO, CARCINOGENIC RISKS TO HUMANS], <https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono93.pdf> [<https://perma.cc/3Y7B-CUEF>] (stating “[p]erineal use of talc-based body powder is possibly carcinogenic to humans”); *Ovarian Cancer Risk Factors*, AM. CANCER SOC’Y (Jan. 26, 2021), <https://www.cancer.org/cancer/ovarian-cancer/causes-risks-prevention/risk-factors.html> [<https://perma.cc/D793-2HE3>].

²⁷⁴ See Johnson & Johnson, Annual Report (Form 10-K), at 84-86 (Feb. 22, 2021); see also Bausch Health Cos., Inc., Annual Report (Form 10-K), at F-66 to F-69 (Feb. 18, 2021); Colgate-Palmolive Co., Annual Report (Form 10-K), at 23 (Jan. 31, 2021).

25,000 plaintiffs with direct claims in pending lawsuits with respect to body powders containing talc.²⁷⁵ One such case was *Ingham v. Johnson & Johnson*.²⁷⁶

Ingham was initially brought in Missouri state court.²⁷⁷ The plaintiffs included twenty-two women (or their estates), and the spouses of some of the women.²⁷⁸ The plaintiffs' allegations included that the "Defendants have known for decades that 'Johnson's Baby Powder' and 'Shower to Shower' contain asbestos fibers . . . , asbestiform fibers . . . , and other dangerous carcinogens, and that these carcinogens cause ovarian cancer."²⁷⁹ They sought recovery "as a result of developing ovarian cancer," which they alleged, "was directly and proximately caused by such wrongful conduct by Defendants, the unreasonably dangerous and defective nature of the PRODUCTS and the attendant effects of developing ovarian cancer."²⁸⁰ The plaintiffs' claims included, among others, strict liability for failure to warn,²⁸¹ negligence,²⁸² breach of express warranty

²⁷⁵ Johnson & Johnson, Annual Report (Form 10-K), at 85 (Feb. 22, 2021). Lawsuits against the company with respect to talc containing powders have been filed in state and federal courts. *See id.* at 88. The annual report indicates that "[t]he majority . . . are pending in federal court, organized into a multi-district litigation (MDL) in the United States District Court for the District of New Jersey." *Id.* at 86; *see also In re Johnson & Johnson*, 509 F. Supp. 3d 116, 128 (D.N.J. 2020); *Johnson & Johnson Talcum Powder Litigation*, U.S. DIST. CT. FOR THE DIST. OF N.J., <https://www.njd.uscourts.gov/johnson-johnson-talcum-powder-litigation> [<https://perma.cc/QD26-3LR4>] (last visited Jan. 17, 2022). A transfer order for the MDL states that all of the actions at issue "share common factual questions arising out of allegations that perineal use of Johnson & Johnson's talcum powder products can cause ovarian or uterine cancer in women" and that "[a]ll the actions involve factual questions relating to the risk of cancer posed by talc and talc-based body powders, whether the defendants knew or should have known of this alleged risk, and whether defendants provided adequate instructions and warnings with respect to the products." Transfer Order, *In re Johnson & Johnson Talcum Powder Prods. Mktg.*, 220 F. Supp. 3d 1356, 1357 (J.P.M.L. 2016), ECF No. 134. As noted earlier, some verdicts for plaintiffs have been overturned on appeal. *See Johnson & Johnson, supra*, at 86.

²⁷⁶ No. 4:17-cv-01857, 2017 WL 3034696 (E.D. Mo. July 18, 2017).

²⁷⁷ *See id.* at *1 (noting that case was initially filed in Missouri state court on August 20, 2015).

²⁷⁸ The plaintiffs' initial petition named eighty-two plaintiffs. *See Ingham v. Johnson & Johnson*, 608 S.W.3d 663, 667 n.1, 724 (Mo. Ct. App. 2020) (noting, however, that "[o]nly twenty-two plaintiffs and their spouses [went] to trial"), *reh'g and/or transfer denied*, (July 28, 2020), *transfer denied*, (Nov. 3, 2020), and *cert. denied*, 141 S. Ct. 2716 (2021).

²⁷⁹ Fifth Amended Petition para. 2, at 4, *Ingham*, No. 1522-cc-10417-01, 2018 WL 3005245 (Mo. Cir. Ct. filed June 5, 2018).

²⁸⁰ *Id.* para. 5, at 6. The petition named Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., and Imerys Talc America, Inc., as defendants. *Id.* at 4. Imerys Talc America, Inc., which had supplied the talc in the products, settled before trial. *See Imerys Unit Settles Talc Claims for at Least \$5 Million: Bloomberg*, REUTERS (June 1, 2018, 11:26 AM), <https://www.reuters.com/article/us-imerys-cancer-lawsuit/imerys-unit-settles-talc-claims-for-at-least-5-million-bloomberg-idUSKCN1IX5D3> [<https://perma.cc/6549-CWYM>].

²⁸¹ Fifth Amended Petition, *supra* note 279, paras. 105-15, at 40-43.

²⁸² *Id.* paras. 116-29, at 43-47.

and breach of implied warranties,²⁸³ and negligent misrepresentation.²⁸⁴ The jury returned verdicts for the plaintiffs based on strict liability and negligence; assessed “punitive damages” and “damages for aggravating circumstances”;²⁸⁵ and awarded the plaintiffs \$4.69 billion in damages, of which \$4.14 billion were in punitive damages.²⁸⁶ The defendants moved for a judgment notwithstanding the verdict on all of the plaintiffs’ claims, which the state trial court denied.²⁸⁷ On appeal, the state appellate court reduced the award to \$2.2 billion, finding that the trial court lacked personal jurisdiction for some nonresident plaintiffs.²⁸⁸ The Missouri Supreme Court declined to review the decision.²⁸⁹ The defendants then petitioned the United States Supreme Court for a writ of certiorari, which was also denied.²⁹⁰

²⁸³ The Plaintiffs brought these claims only against the Johnson & Johnson defendants. *Id.* paras. 130-39, at 47-49.

²⁸⁴ *Id.* paras. 154-60, at 54-55.

²⁸⁵ *See, e.g.*, Verdict, Agreement and Settlement at 29-31, 44-46, *Ingham v. Johnson & Johnson*, No. 1522-cc-10417-01, 2018 WL 3493338 (Mo. Cir. Ct. filed July 12, 2018); *see also* Verdict at 3, 6, *Ingham*, No. 1522-cc-10417-01, 2018 WL 3493335 (Mo. Cir. Ct. filed July 12, 2018).

²⁸⁶ *See, e.g.*, Tiffany Hsu, *Johnson & Johnson Loses Bid to Overturn Verdict*, N.Y. TIMES, Dec. 20, 2018, at B2.

²⁸⁷ Order Denying Defendants’ Post Trial Motions at 1, 10, *Ingham*, No. 1522-cc-10417-01, 2018 WL 7960293 (Mo. Cir. Ct. filed Dec. 19, 2018). In denying the motion, the court noted that it had previously considered Defendants’ preemption argument on the issue of the Plaintiffs’ failure to warn claims and found they were not preempted. *Id.* at 4.

²⁸⁸ *Ingham*, 608 S.W.3d 663, 724 (Mo. Ct. App. 2020) (entering judgment for \$625 million in total actual damages, \$900 million in punitive damages against Johnson & Johnson Consumer Companies, Inc., and almost \$716 million in punitive damages against Johnson & Johnson), *cert. denied*, 141 S. Ct. 2716 (2021).

²⁸⁹ *Id.*

²⁹⁰ *See id.*; *Ingham*, 141 S. Ct. 2716, 2716 (2021) (denying certiorari).

C. Preemption

Defendants in cases concerning cosmetic talc, including *Ingham*, have raised preemption as a defense.²⁹¹ In one case, *Feinberg v. Colgate-Palmolive Co.*,²⁹² the New York County Supreme Court considered the express preemption provision in section 379s of the United States Code (section 752 of the FDCA).²⁹³ *Feinberg* involved a personal injury action in which the plaintiff claimed her injury was a result of her alleged exposure to asbestos in talcum powder.²⁹⁴ The New York County Supreme Court denied the defendant's motion to dismiss on the basis that the express preemption clause in section 379s did not apply retroactively.²⁹⁵ However, it noted in the course of its analysis that the "saving clause" in section 379s "expressly permits Plaintiff's products liability claims" and "demonstrates Congressional intent not to impair such preexisting rights."²⁹⁶

The New York court also considered whether there was "any specific [state] requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under [the FDCA] for packaging or labeling."²⁹⁷ The state court concluded that FDA's denial of a citizen petition seeking an asbestos warning on cosmetic talc was not such a requirement.²⁹⁸ Finally, the court also rejected the defendant's implied preemption argument that "requiring a warning on its talc products would obstruct the purposes and objectives of the FDA's labeling requirements" as without merit.²⁹⁹

²⁹¹ See Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Motion and Memorandum of Law in Support of Motion for Judgment Notwithstanding the Verdict at 36, *Ingham*, No. 1522-cc-10417-01, 2018 WL 7079682 (Mo. Cir. Ct. filed Sept. 20, 2018) (arguing that "Defendants are . . . entitled to judgment notwithstanding the verdict as to plaintiffs' claims for failure to warn because they are preempted"); see also Order, *supra* note 287, at 4 ("This Court has previously considered Defendants' preemption argument on this issue and found that Plaintiffs' claims were not preempted."); Defendants Johnson & Johnson and Johnson & Johnson Consumer Inc.'s Motion for Directed Verdict at the Close of Plaintiffs' Case at 1, *Ingham*, No. 1522-cc-10417-01, 2018 WL 3446972 (Mo. Cir. Ct. filed June 27, 2018) (arguing that "[t]he Johnson & Johnson Defendants are entitled to a directed verdict on plaintiffs' claims because the claims are preempted"); *Johnson & Johnson v. Fitch ex rel. State*, 2019-IA-00033-SCT (¶ 29), 315 So. 3d 1017, 1025 (Miss. 2021) (holding, in a case brought by the Mississippi Attorney General under the Mississippi Consumer Protection Act, that the state's claim was not barred by express or implied preemption "because of the lack of any specific requirement by the [FDA]").

²⁹² *Feinberg v. Colgate-Palmolive Co.*, No. 190070/11, 2012 WL 954271 (N.Y. Sup. Ct. Mar. 22, 2012).

²⁹³ *Id.* at *1.

²⁹⁴ *Id.*

²⁹⁵ *Id.* at *2-3.

²⁹⁶ *Id.* at *2, *9.

²⁹⁷ *Id.* at *6 (first alteration in original) (quoting 21 U.S.C. § 379s(c)).

²⁹⁸ *Id.*

²⁹⁹ *Id.* at *10.

D. *FDA & (A Lack of) Regulation of Cosmetic-Talc Products*

The products at issue in *Ingham* that the plaintiffs' alleged caused their injuries contained talcum powder (i.e., talc).³⁰⁰ Talc body powders meet the definition of "cosmetic" discussed in Section I.A because they are "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance."³⁰¹

As cosmetics, talc body powders are regulated under the regulatory framework for cosmetics, a framework which, as discussed in Section I.C.1.b, has substantial limitations. There is no premarket approval requirement for cosmetics.³⁰² Instead, FDA must act to remove a cosmetic from the market if it is in violation of the FDCA, and the burden of proving that a cosmetic is adulterated or misbranded, for example, falls on the government.³⁰³

In 1983, Phillippe Douillet petitioned FDA to request, among other things, "a label of warning of the hazardous effects produced by asbestos with the continuous use of cosmetic talc."³⁰⁴ FDA denied the petition in 1986.³⁰⁵ In so doing, FDA noted that in "the early 1970s, FDA became concerned about the possibility that cosmetic talc did contain significant amounts of [asbestiform minerals,]" but that "the agency was not able to assess reliably the levels of asbestiform minerals in cosmetic talc then [sic] in the marketplace."³⁰⁶ The agency's response to the citizen petition also states that it "request[ed] assistance from the affected industry in developing acceptable analytical procedures," which "apparently ha[d] led to considerable improvement in the quality of this talc" and that "FDA surveillance activities that were conducted in the latter portion of the 1970s showed that the quality of cosmetic talc had significantly improved, and that even when asbestos was present, the levels were so low that no health hazard existed."³⁰⁷ FDA also noted that it found "several problems with the information on which" the petitioner had relied.³⁰⁸

³⁰⁰ *Ingham v. Johnson & Johnson*, 608 S.W.3d 663, 678 (Mo. Ct. App. 2020), *reh'g and/or transfer denied*, (July 28, 2020), *transfer denied*, (Nov. 3, 2020), and *cert. denied*, 141 S. Ct. 2716 (2021).

³⁰¹ Federal Food, Drug, and Cosmetic Act (FDCA) § 201(i), 21 U.S.C. § 321(i).

³⁰² See *supra* Section I.C.1.

³⁰³ See *supra* Section I.C.1.

³⁰⁴ See Phillippe Douillet, Petition Letter to U.S. FDA for Labeling of Warning of the Hazardous Effects Produced by Asbestos in Cosmetic Talc, FDA00003597 (Nov. 8, 1983), <https://www.reuters.com/investigates/special-report/assets/usa-health-fda-talc/douillet-petition.pdf> [<https://perma.cc/EW83-FCMA>].

³⁰⁵ See J. W. Swanson, Acting Assoc. Comm'r for Regul. Affs., U.S. FDA, Denial of Petition of Phillippe Douillet, No. 83P-404, at 5 (July 11, 1986), https://www.factsabouttalc.com/_document/d-7214?id=0000016c-4ab3-d15b-a3ec-caf365d40000 [<https://perma.cc/XSG7-DHET>].

³⁰⁶ *Id.* at 3.

³⁰⁷ *Id.* at 4.

³⁰⁸ *Id.*

The Cancer Prevention Coalition later petitioned FDA twice to require cancer warnings on cosmetic-talc products.³⁰⁹ In 1994, the Coalition petitioned FDA to require “a warning such as . . . ‘Frequent talc application in the female genital area increases the risk of ovarian cancer,’” stating that “scientific papers dating back to the 1960s . . . warn of increased cancer rates resulting from frequent exposure to cosmetic grade talc.”³¹⁰ The Coalition petitioned FDA again in 2008, requesting the same.³¹¹ FDA denied both petitions.³¹² In its 2014 denial, FDA stated that it “did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer.”³¹³

From 2009 to 2010, FDA surveyed cosmetic talc. Its “survey found no asbestos fibers or structures.”³¹⁴ However, FDA noted that the results were limited because of the nine talc suppliers it identified, only “four complied with the [survey] request.”³¹⁵ Because of survey limitations, FDA noted that the results “do not prove that most or all talc or talc-containing cosmetic products currently marketed in the United States are likely to be free of asbestos contamination.”³¹⁶

As noted earlier, FDA undertook another survey in 2019, following reports of talc-containing cosmetics containing asbestos. In contrast to its earlier survey, FDA announced that products from several different distributors and manufacturers tested positive for asbestos.³¹⁷ Following the testing, the limitations of FDA’s cosmetic authority were apparent.³¹⁸ FDA indicated that one of the companies that it requested recall products “refused to comply” with

³⁰⁹ See Samuel S. Epstein, Cancer Prevention Coal., Citizen Petition to U.S. FDA Seeking Carcinogenic Labeling on All Cosmetic Talc Products, FDA00000222 (Nov. 17, 1994) [hereinafter Carcinogenic Labeling Petition], <https://www.reuters.com/investigates/special-report/assets/usa-health-fda-talc/epstein-petition.pdf> [https://perma.cc/DA8Q-L4W3]; Samuel S. Epstein, Cancer Prevention Coal., Citizen Petition to U.S. FDA Seeking a Cancer Warning on Cosmetic Talc Products, FDA.2008.P.0309, at 2 (May 13, 2008) [hereinafter Cancer Warning Petition] (on file with *Boston University Law Review*) (referencing the 1994 Citizen Petition submitted by the Cancer Prevention Coalition).

³¹⁰ Carcinogenic Labeling Petition, *supra* note 309, at 1.

³¹¹ Cancer Warning Petition, *supra* note 309, at 1.

³¹² See Steven M. Musser, Deputy Dir. Sci. Operations, Ctr. for Food Safety & Applied Nutrition, U.S. FDA, Denial of Two Citizen Petitions of Samuel S. Epstein, Pltf_Misc_00000382, 6 (Apr. 1, 2014), <https://www.reuters.com/investigates/special-report/assets/usa-health-fda-talc/epstein-response.pdf> [https://perma.cc/JL8R-WKLA].

³¹³ *Id.* at 1.

³¹⁴ *Talc*, *supra* note 100 (select “FDA’s Talc Survey of 2009-2010” dropdown).

³¹⁵ *Id.* (select “FDA’s Talc Survey of 2009-2010” dropdown).

³¹⁶ *Id.* (select “FDA’s Talc Survey of 2009-2010” dropdown).

³¹⁷ *FDA Summary of Results*, *supra* note 266.

³¹⁸ Statement from FDA Commissioner, *supra* note 1 (“These findings serve as an important reminder that under our current authority, the FDA has only limited tools to ensure the safety of cosmetics products.”).

its request and that it “does not have authority to mandate a recall.”³¹⁹ Several companies voluntarily recalled products, including ultimately the company that FDA had indicated initially refused.³²⁰ More recently, on February 4, 2020, “FDA held a public meeting on testing methods for asbestos in talc and cosmetic products containing talc.”³²¹

E. *Gender, Race & Talc Body Powder*

Body powders and their use also reflect how cosmetic use, gender, and race are intertwined. Body powders have long been specifically marketed to women. According to the National Museum of American History’s website, pre-twentieth century, “[t]alcum powder was sold as a general body freshener and deodorant” and “advertisers often specifically targeted women, whom they implied were most at risk for offensive body odors.”³²² The advertising reflected different expectations for women and men: women’s bodies, according to advertisers, were expected to have “a general ‘sweetness’” and “should be without body odor”—expectations that did not extend to men.³²³

The plaintiffs in *Ingham* alleged that “[t]he bottle of ‘Johnson’s Baby Powder’ specifically targets women, by stating, ‘For you, use every day to help feel soft, fresh, and comfortable.’”³²⁴ In addition, Reuters has reported that in the 1950s and 1960s Johnson’s Baby Powder was “[l]osing the connection to the product’s namesake—babies,” following case studies “point[ing] to the dangers of breathing in talc” and a report “citing the deaths of three children who inhaled large amounts of talcum powder,” which “left J&J eager to cultivate other

³¹⁹ *Id.*

³²⁰ *See id.*; Press Release, U.S. FDA, Baby Powder Manufacturer Voluntarily Recalls Products for Asbestos (Oct. 18, 2019), <https://www.fda.gov/news-events/press-announcements/baby-powder-manufacturer-voluntarily-recalls-products-asbestos> [<https://perma.cc/JML3-577G>]; *see also* FDA Advises Consumers, *supra* note 4 (indicating that Johnson & Johnson, Beauty Plus Global, and Claire’s, Inc., voluntarily recalled some product).

³²¹ *See Public Meeting on Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc*, U.S. FDA (Aug. 18, 2020), <https://www.fda.gov/cosmetics/cosmetics-news-events/public-meeting-testing-methods-asbestos-talc-and-cosmetic-products-containing-talc-02042020-02042020> [<https://perma.cc/W3VH-QBR9>]. In late 2021, FDA announced the results of its 2020-2021 sampling of talc-containing cosmetics, indicating that “all 50 samples tested negative for detectable asbestos” and that FDA will test another 50 samples in 2022. *FDA in Brief: FDA Makes Progress on Efforts to Understand Presence of Asbestos in Cosmetic Products*, U.S. FDA (Oct. 25, 2021), <https://www.fda.gov/news-events/press-announcements/fda-brief-fda-makes-progress-efforts-understand-presence-asbestos-cosmetic-products#:~:text=Additional%20Information,assessed%20were%20negative%20for%20asbestos> [<https://perma.cc/3ABP-FGRS>].

³²² *Alleviating Body Odors*, SMITHSONIAN INST., <https://www.si.edu/spotlight/health-hygiene-and-beauty/alleviating-body-odors#ogmt-edan-search-results> [<https://perma.cc/27DB-4J8A>] (last visited Jan. 17, 2022).

³²³ *Id.*

³²⁴ Fifth Amended Petition, *supra* note 279, para. 57, at 28.

markets.”³²⁵ The article states that “[b]eginning in the 1970s, J&J ran ads clearly intended to woo young women” and that in 1989, an “advertising firm . . . submitted a plan to J&J to ‘initiate a high level of usage’ among young women,” which “would try to convince teen girls that Johnson’s Baby Powder, ‘applied daily after showering, is a simple, *feminine* way to smell clean and fresh during the day.’”³²⁶ In this way, cosmetic use is both shaped by *and* shapes gender.

Body powders may also have been specifically marketed to African-American women.³²⁷ Reuters reported that “[t]he ‘right place’ to focus, according to a 2006 internal J&J marketing presentation, was ‘under developed geographical areas with hot weather, and higher AA population,’ the ‘AA’

³²⁵ Chris Kirkham & Lisa Girion, *Special Report: As Baby Powder Concerns Mounted, J&J Focused Marketing on Minority, Overweight Women*, REUTERS (Apr. 9, 2019, 9:08 AM), <https://www.reuters.com/article/us-johnson-johnson-marketing-specialrepo/specia-l-report-as-baby-powder-concerns-mounted-jj-focused-marketing-on-minority-overweight-women-idUSKCN1RL1JZ> [<https://perma.cc/TC5W-RKZL>].

³²⁶ *Id.* (emphasis added).

³²⁷ At the time that this Article was written, lawsuits brought by two states against several companies concerning talc-containing products were pending. *See generally* Appendix to Petition of Johnson & Johnson; Johnson & Johnson Consumer Companies, Inc.; Valeant Pharmaceuticals International, Inc.; and Valeant Pharmaceuticals North America LLC for Interlocutory Appeal by Permission, *Johnson & Johnson v. Hood ex rel. State*, No. 2019-M-00033 (Miss. 2019) [hereinafter Appendix to Petition of Johnson & Johnson], <https://www.courts.ms.gov/appellatecourts/docket/sendPDF.php?f=web0001.SCT.2019-M-33.9402.0.pdf&c=89527&a=N&s=2> [<https://perma.cc/V75A-VN63>]; Press Release, New Mexico Att’y Gen., Attorney General Balderas Files Suit Against Manufacturers of Talcum Powder (Jan. 2, 2020) [hereinafter Balderas Press Release], https://www.nmag.gov/uploads/PressRelease/48737699ae174b30ac51a7eb286e661f/AG_Files_Suit_Against_Manufacturer_s_of_Talcum_Powder.pdf [<https://perma.cc/5J7J-MDTL>] (discussing case pending in New Mexico and attaching complaint filed by Attorney General Hector H. Balderas). A complaint filed by the Attorney General of Mississippi alleged violations of the state’s consumer protection act. Appendix to Petition of Johnson & Johnson, *supra*, para. 1, at APPENDIX.0005. The lawsuit alleges that the defendant companies “engaged in misrepresentations and omissions in connection with the labeling, advertisements, promotion, marketing, and sale of their Talc Products” and that they “intentionally targeted minority communities.” *Id.* paras. 5, 9, at APPENDIX.0006-08 (alleging that “[t]he State has a quasi-sovereign interest in ensuring that companies do not . . . engage in discriminatory marketing putting a specific portion of the population at greater risk”). A complaint filed by the Attorney General of New Mexico alleged violations of various acts of that state and “common law and equitable causes of action.” Balderas Press Release, *supra* para. 1, at 1. *See generally id.* (reporting that Attorney General’s Office is prepared to take action against corporations that mislead or endanger its constituents). The lawsuit alleges that “[t]o ‘grow the franchise,’ the [named] company implemented a strategy of targeting African-American and Hispanic women,” that “[t]he racially targeted strategy implemented by J&J has and continues to disproportionately affect the citizens of New Mexico because approximately forty-eight (48%) of New Mexico’s population is comprised of African-American and Hispanic individuals,” and that “the companies [named in the lawsuit] that manufacture and sell talc products have concealed and failed to warn consumers about the dangerous associated with their Talc Products.” *Id.* paras. 87-88, at 29-30.

referring to African-Americans.³²⁸ According to Reuters, the company “turned those proposals into action.”³²⁹

Body powder use may be more common in African-American women than in other women.³³⁰ For example, Ami R. Zota and Bhavna Shamasunder write that the “[u]se of talc powder on the genitals is [a] practice that is practiced disproportionately by US African American women.”³³¹ Target marketing may “foster[] and maintain[] insecurities about body odors—particularly vulvar odors—among African-American women.”³³² Moreover, “the use of vaginal deodorants such as douche preparations and aerosolized sprays,” practices which may be seen as cultural norms and an aspect of African American beauty culture, may have troubling racial implications rooted in “the history of racist beliefs about the Black body.”³³³

F. Ovarian Cancer & Health & Healthcare Disparities

As noted earlier, whether talcum powder use was the cause of the plaintiffs’ ovarian cancer—e.g., as the plaintiffs in *Ingham* alleged³³⁴—is one of the disputed questions in the context of the cosmetic-talc cases. But setting aside the

³²⁸ Kirkham & Girion, *supra* note 325.

³²⁹ *Id.* (“[Johnson & Johnson] distributed Baby Powder samples through churches and beauty salons in African-American and Hispanic neighborhoods, ran digital and print promotions with weight-loss and wellness company Weight Watchers and launched a \$300,000 radio advertising campaign in a half-dozen markets aiming to reach ‘curvy Southern women 18-49 skewing African American.’”).

³³⁰ Joellen M. Schildkraut, Sarah E. Abbott, Anthony J. Alberg, Elisa V. Bandera, Jill S. Barnholtz-Sloan, Melissa L. Bondy, Michele L. Cote, Ellen Funkhouser, Lauren C. Peres, Edward S. Peters, Ann G. Schwartz, Paul Terry, Sydnee Crankshaw, Fabian Camacho, Frances Wang & Patricia G. Moorman, *Association Between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology Study (AACES)*, 25 *CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION* 1411, 1416 (2016), (noting a “high prevalence of exposure to both genital and nongenital body powder among [African American] women compared with the mostly white subjects”); Britton Trabert, *Commentary, Body Powder and Ovarian Cancer Risk—What Is the Role of Recall Bias?*, 25 *CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION* 1369, 1369-70 (2016) (stating that “[t]he prevalence of body powder use is reported to be higher among African American women than among non-Hispanic white women,” but noting possible recall bias as a result of media coverage); Anna H. Wu, Celeste L. Pearce, Chiu-Chen Tseng & Malcolm C. Pike, *African Americans and Hispanics Remain at Lower Risk of Ovarian Cancer than Non-Hispanic Whites After Considering Nongenetic Risk Factors and Oophorectomy Rates*, 24 *CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION* 1094, 1096 (2015) (“Talc use was more common in African-American women . . . than in non-Hispanic Whites . . . or Hispanics . . .”).

³³¹ Zota & Shamasunder, *supra* note 34, at 420.

³³² Michelle Ferranti, *An Odor of Racism: Vaginal Deodorants in African-American Beauty Culture and Advertising*, 11 *ADVERT. & SOC’Y REV.*, no. 4, 2011, <https://muse.jhu.edu/article/407304>.

³³³ *Id.*

³³⁴ *See* Order, *supra* note 287, at 3 (holding that the plaintiffs in *Ingham* satisfied the standard for causation under Missouri state law).

question of causation for a moment, ovarian cancer can be used to examine disparities in health and healthcare.

Ovarian cancer is cancer of the female reproductive organs, the ovaries.³³⁵ As a result, it primarily develops in women.³³⁶ Research on National Cancer Institute funding and the Funding to Lethality score for ovarian cancer has found that ovarian cancer research is “significantly underfunded” compared to other cancers.³³⁷ This may negatively impact the trials available to patients with ovarian cancer, trial enrollment, and the number of treatment recommendations.³³⁸

There are significant racial disparities in access to ovarian cancer treatment and outcomes. African American women have a lower ovarian cancer rate than non-Hispanic White women but a higher death rate.³³⁹ For example, one study found that “differences in access to care” may be “responsible for the widening of survival differences between African American and White women over time.”³⁴⁰ In addition, a review found that there was “evidence of continued and significant disparities in ovarian cancer treatment and mortality, especially among black patients.”³⁴¹ The meta-analysis “showed a statistically significant

³³⁵ *Key Statistics for Ovarian Cancer*, AM. CANCER SOC’Y (Jan. 12, 2021), <https://www.cancer.org/cancer/ovarian-cancer/about/key-statistics.html> [<https://perma.cc/72EY-CU6U>]. It can also develop in transgender men and other people who were born with ovaries who do not identify as women. *See Ovarian Cancer in Transgender Men*, NAT’L LGBT CANCER NETWORK, <https://cancer-network.org/cancer-information/transgendergender-nonconforming-people-and-cancer/ovarian-cancer-in-transgender-men/> [<https://perma.cc/UG3K-LYUV>] (last visited Jan. 17, 2022) (explaining risks of ovarian cancer for transgender men).

³³⁶ *Key Statistics for Ovarian Cancer*, *supra* note 335.

³³⁷ Ryan J. Spencer, Laurel W. Rice, Clara Ye, Kaitlin Woo & Shitanshu Uppal, *Disparities in the Allocation of Research Funding to Gynecologic Cancers by Funding to Lethality Scores*, 152 GYNECOLOGIC ONCOLOGY 106, 107 (2019).

³³⁸ *Id.* at 108. This may also impact potential plaintiffs’ ability to establish the cause of their ovarian cancer in product liability cases. *See* Rachael Casey & Timothy P. Larkin, *Ovarian Cancer and ‘Tainted Talc’: What Treating Physicians Need to Know*, 116 MO. MED. 83, 84 (2019) (postulating that the “less-than-compelling scientific record” linking talc to ovarian cancer may be “the reason for the recent shift in litigation strategy” towards blaming ovarian cancer on asbestos). *See generally* Leslie I. Boden & David Ozonoff, *Litigation-Generated Science: Why Should We Care?*, 116 ENV’T HEALTH PERSPS. 117 (2008) (discussing courts’ general preference for existing science over “litigation-generated science”).

³³⁹ Eudocia Lee & Patrick Wen, *Gender and Sex Disparity in Cancer Trials*, 5 ESMO OPEN, Aug. 2020, at 3.

³⁴⁰ Mishka Terplan, Nicholas Schluterman, Erica J. McNamara, J. Kathleen Tracy & Sarah M. Temkin, *Have Racial Disparities in Ovarian Cancer Increased Over Time? An Analysis of SEER Data*, 125 GYNECOLOGIC ONCOLOGY 19, 23 (2012).

³⁴¹ Shama Karanth, Mackenzie E. Fowler, XiHua Mao, Lauren E. Wilson, Bin Huang, Maria Pisu, Arnold Potosky, Tom Tucker & Tomi Akinyemiju, *Race, Socioeconomic Status, and Health-Care Access Disparities in Ovarian Cancer Treatment and Mortality: Systematic Review and Meta-Analysis*, JNCI CANCER SPECTRUM, Oct. 9, 2019, at 10.

25% reduction in likelihood of guideline-adherent treatment among blacks compared with whites” and “a statistically significant 18% higher risk of ovarian cancer mortality compared with whites.”³⁴² At the same time, there has been limited research on ovarian cancer in African American women,³⁴³ and African American women are less likely than White women to enroll in ovarian cancer trials.³⁴⁴

Studies of whether there is an association between talc genital powder use and ovarian cancer have been mixed, and the IARC has identified it as possibly carcinogenic.³⁴⁵ A study of talc body powder use and ovarian cancer in African American women “found that the application of genital powder is associated with serous and nonserous [epithelial ovarian cancer].”³⁴⁶

G. *Gender, Race & Asbestos Litigation*

The preemption of state tort law claims in the cosmetic context may also raise equity concerns given that asbestos claims are gendered and reflect gender- and race-based disparities in the tort system.

In prior asbestos litigation, “[m]en were disproportionately victimized, being exposed to asbestos in the military, in shipyards, in mines and in other male-oriented occupations,”³⁴⁷ “occupations from which women were largely excluded.”³⁴⁸ In contrast, many plaintiffs in the cosmetic-talc cases are women.³⁴⁹ Whereas asbestos litigation has been described as “exemplif[ying]

³⁴² *Id.* at 6.

³⁴³ Patricia G. Moorman, Rachel T. Palmieri, Lucy Akushevich, Andrew Berchuck & Joellen M. Schildkraut, *Ovarian Cancer Risk Factors in African-American and White Women*, 170 AM. J. EPIDEMIOLOGY 598, 598 (2009) (stating that “[d]espite the importance of ovarian cancer as a major cause of morbidity and mortality, there has been very little research on ovarian cancer among African Americans”); see also *Ovarian Cancer Studies Aim to Reduce Racial Disparities, Improve Outcomes*, NAT’L CANCER INST. (July 16, 2020), <https://www.cancer.gov/news-events/cancer-currents-blog/2020/ovarian-cancer-racial-disparities-studies> [<https://perma.cc/53YG-3D5U>] (stating that “a lack of data on ovarian cancer among diverse populations has impeded research in this area”).

³⁴⁴ Lee & Wen, *supra* note 339, at 3.

³⁴⁵ See generally WHO, CARCINOGENIC RISKS TO HUMANS, *supra* note 273, at 412 (“Perineal use of talc-based body powder is possibly carcinogenic to humans” (emphasis omitted)); Schildkraut et al., *supra* note 330; Trabert, *supra* note 330.

³⁴⁶ Schildkraut et al., *supra* note 330, at 1416. *But see* Trabert, *supra* note 330, at 1369 (“[T]wo prospective cohort studies—which assessed genital powder use prior to cancer development—did not support increased risk of overall ovarian cancer . . .”).

³⁴⁷ Koenig & Rustad, *supra* note 170, at 35.

³⁴⁸ *Id.* at 36 n.133; see also Michelle J. White, *Understanding the Asbestos Crisis* 12 (May 2003) (unpublished manuscript), <https://law.yale.edu/sites/default/files/documents/pdf/white.pdf> [<https://perma.cc/4AGQ-JNBZ>] (stating that “virtually all” of the plaintiffs in the examined asbestos trials were male).

³⁴⁹ See Transfer Order, *In re Johnson & Johnson Talcum Powder Prods. Mktg.*, 220 F. Supp. 3d 1356, 1357 (J.P.M.L. 2016) (noting that the shared factual questions arise out of

male-gendered products liability,³⁵⁰ the current litigation may be described as exemplifying female-gendered products liability. For example, in *Ingham*, the plaintiffs claimed injuries—ovarian cancer—to part of the female reproductive system—the ovaries—that they alleged were caused by a highly gendered product—cosmetics—that they allege had asbestos.³⁵¹

In a 2014 article, Anita Bernstein describes American male asbestos plaintiffs being treated with “unprecedented generosity” and “[e]xtraordinary favoritism” within the tort system and experiencing “extraordinary success.”³⁵² When women made asbestos claims outside of the cosmetic context—e.g., after “inhal[ing] fibers that her husband, an asbestos worker, brought home from his job” while doing his laundry, Bernstein notes, “[c]ourts have almost unanimously denied [such] claims.”³⁵³ Bernstein contends that there are a variety of gender disparities in asbestos law that are “contrary to the material interests of women,” including that men and women who suffered comparable harms did not fare comparably in court.³⁵⁴ Women “fared worse.”³⁵⁵

Asbestos plaintiffs of color fared worse than White plaintiffs in prior asbestos cases. For example, they are not immune from the race-based disparities in damages awards that result from the use of race-based life expectancy statistics.³⁵⁶ For example, in *Torts and Discrimination*, which was discussed in Section II.B.2, authors Ronen Avraham and Kimberly Yuracko cite a 1994 asbestos case in which the Sixth Circuit Court of Appeals upheld “the trial court’s use of a standard life expectancy table particularized to the plaintiff’s race and gender in calculating life expectancy for future pain and suffering

allegations that use of the “products can cause ovarian or uterine cancer *in women*” (emphasis added)); Kirkham & Girion, *supra* note 325 (“[W]omen . . . make up a large number of the 13,000 plaintiffs alleging that J&J’s [products] . . . caused their ovarian cancer or mesothelioma.”).

³⁵⁰ Bernstein, *supra* note 160, at 303.

³⁵¹ Fifth Amended Petition, *supra* note 279, paras. 1-2, at 4.

³⁵² Bernstein, *supra* note 243, at 1214, 1225.

³⁵³ *Id.* at 1216, 1222.

³⁵⁴ *Id.* at 1213; *see also id.* at 1225-45 (discussing how men fared better than comparably harmed women in courts).

³⁵⁵ *Id.* at 1257.

³⁵⁶ *See* Avraham & Yuracko, *supra* note 197, at 672 & n.46.

damages.”³⁵⁷ Additionally, one study found disparities between people of color and White plaintiff settlement amounts in asbestos cases.³⁵⁸

H. *How Tort Law May Complement & Reinforce the Regulation of Cosmetics*

Earlier, this Article explored how tort law may complement and reinforce the regulation of cosmetics.³⁵⁹ This Section returns to that question and considers what the examination in the current Part, including the examination of *Ingham*, adds.

Talc body powders provide an example of how product use may vary by gender and race and how products may be marketed specifically to women and people of color.³⁶⁰ When used to control odor, talc body powder is intimately intertwined with issues of social identity and control of female bodies.³⁶¹ Against this backdrop, tort law may help empower women, including those who are members of other historically excluded groups, by providing the possibility of redress.

In addition, tort law in the cosmetic context may provide compensation to injured persons. In *Ingham*, the twenty women who claimed that the cosmetic-talc products at issue caused their ovarian cancer were ultimately awarded a total of approximately \$2.2 billion.³⁶²

However, *Ingham* also reflects one of the limitations of tort law: the inability of tort law to make a person who suffered an injury whole. The respondents’ lawyers indicated in an April 2021 brief that “[s]ix respondents (represented by

³⁵⁷ *Id.* (citing *Adkins v. Asbestos Corp.*, 18 F.3d 1349, 1350-51 (6th Cir. 1994)). According to the U.S. life tables, the life expectancy for a “Non-Hispanic black” one-year-old is 74.5 years, whereas it is 78 years for a “Non-Hispanic white” one-year-old. Elizabeth Arias & Jiaquan Xu, *United States Life Tables, 2018*, 69 NAT’L VITAL STATS. REPS., at 3 tbl.A (Nov. 17, 2020), <https://www.cdc.gov/nchs/data/nvsr/nvsr69/nvsr69-12-508.pdf> [<https://perma.cc/Q5W2-28GW>]. The life expectancy for females of both races is higher than that of same-race males, with “Non-Hispanic white” females having the highest life expectancy. *See id.* While this may tend to increase damages awards for females compared to males, the use of worklife expectancy tables and wage tables may cut the other way. *See Avraham & Yuracko, supra* note 197, at 670-77 (showing how use of life expectancy, worklife expectancy, and average national wage tables “have infused race and gender bias into damage calculations”).

³⁵⁸ Chamallas, *supra* note 193, at 465-66; *see also* CHARLES Z. SMITH, WASHINGTON STATE MINORITY & JUSTICE TASK FORCE: FINAL REPORT 118-31 (1990), <https://www.courts.wa.gov/committee/pdf/TaskForce.pdf> [<https://perma.cc/HL4W-SQYB>] (finding that “[t]he case settlement data analysis showed that minorities received lower average settlements than non-minorities,” but that further study is needed).

³⁵⁹ *See supra* Section II.B.

³⁶⁰ *See supra* Section III.E.

³⁶¹ *See supra* Section III.E; *see also* Kirkham & Girion, *supra* note 325 (describing supposed proper “feminine way to smell”).

³⁶² *Ingham v. Johnson & Johnson*, 608 S.W.3d 663, 724 (Mo. Ct. App. 2020), *reh’g and/or transfer denied*, (July 28, 2020), *transfer denied*, (Nov. 3, 2020), and *cert. denied*, 141 S. Ct. 2716 (2021).

their estates) had died from ovarian cancer by the time of trial in th[e] case; another three have died from it since.”³⁶³ They also noted that each of the respondents would likely die from ovarian cancer.³⁶⁴ The award in *Ingham* cannot undo their injuries, and thus compensation cannot truly make them whole.³⁶⁵

Tort law may also have a deterrent effect. Companies that manufacture cosmetics may look to the *Ingham* case and take greater safety precautions to avoid similar liability. However, whether this is good, depends on, among other things, whether cosmetic talc is a potentially hazardous substance containing asbestos as the plaintiffs in *Ingham* alleged.³⁶⁶ As discussed above, tort law also has substantial limitations for female and racial minority plaintiffs, including in the context of cosmetics.³⁶⁷ As a result, tort law may underdeter and “create[] *ex ante* incentives for potential tortfeasors that encourage future targeting of disadvantaged groups.”³⁶⁸ Nevertheless, removing tort law may worsen the effects of the cosmetic regulatory system’s failures, failures which may also disproportionately impact women, including those who are members of other excluded groups.

While much of the cosmetic-talc litigation is ongoing, there is some indication that it may also reflect the radiating effects of tort law. Various publications directed toward women and teens have run stories about the litigation or appear to have been influenced by it.³⁶⁹ For example, *Teen Vogue*, an online publication

³⁶³ Brief in Opposition for Respondents at 2, *Ingham*, No. 20-1223 (U.S. Apr. 19, 2021).

³⁶⁴ *Id.* at 17.

³⁶⁵ See Eric A. Posner & Cass R. Sunstein, *Dollars and Death*, 72 U. CHI. L. REV. 537, 558 (2005) (implying that compensation cannot make plaintiff whole again because tort law “monetiz[es] death”); Sean Hannon Williams, *Lost Life and Life Projects*, 87 IND. L.J. 1745, 1763 (2012) (describing how “mak[ing] someone whole would require undoing the injury,” and discussing the challenges which death poses to doing this).

³⁶⁶ Fifth Amended Petition, *supra* note 279, paras. 1-2.

³⁶⁷ See Chamallas, *supra* note 193, at 465-66; see also *supra* Section II.C.2.

³⁶⁸ Avraham & Yuracko, *supra* note 197, at 666-67.

³⁶⁹ See, e.g., De Elizabeth, *A Jury Awarded \$4.69 Billion to Women Accusing Johnson & Johnson of Contributing to Their Ovarian Cancer*, TEEN VOGUE (July 15, 2018), <https://www.teenvogue.com/story/jury-469-billion-women-accusing-johnson-johnson-ovarian-cancer> [<https://perma.cc/9EQX-2BQX>]; Liz Flora, *Talc-Free Is the New Paraben-Free*, GLOSSY (June 18, 2020), <https://www.glossy.co/beauty/talc-free-is-the-new-paraben-free/> [<https://perma.cc/7F53-PUWT>]; Elizabeth Inglese, *Does Baby Powder Contain Asbestos? What Women Need to Know About Johnson & Johnson’s Ovarian Cancer Lawsuit*, VOGUE (Dec. 16, 2018), <https://www.vogue.com/article/talcum-baby-powder-cancer> [<https://perma.cc/JM8S-QVFM>]; Sarah Kinonen, *Johnson & Johnson Was Ordered to Pay a Record-Setting Verdict to This Cancer Patient*, TEEN VOGUE (May 9, 2017), <https://www.teenvogue.com/story/johnson-and-johnson-lawsuit-talc> [<https://perma.cc/378F-9RYB>].

targeted toward young women,³⁷⁰ has run pieces about the litigation.³⁷¹ As another example, fashion magazine *Elle* lists “talc-free beauty” as its number one category in a piece titled *The 2021 ELLE Green Beauty Stars*.³⁷² The piece states that “[t]he 2019 documentary *Toxic Beauty* examined the connection between cancer and talcum powder,” which “drove viewers to study the fine print on their beauty products,” before listing several talc-free cosmetics.³⁷³ The press kit for the film states that it “follows the class action lawsuit against J&J.”³⁷⁴ *Glossy*, a “fashion, luxury and technology” publication,³⁷⁵ in a piece titled *Talc-Free Is the New Paraben-Free*, quoted the founder of a “clean beauty brand” as stating, “[t]he reason that specific focus is on this one ingredient [(talc)] is because of the case that was against Johnson & Johnson. That’s public knowledge.”³⁷⁶ Public visibility of the cosmetic-talc litigation may, in turn, impact beauty culture.³⁷⁷ Indeed, several companies have removed talc-containing products from the market or replaced talc with other ingredients.³⁷⁸ Again, whether this is a good thing may depend on, among other things, whether cosmetic talc is a potentially hazardous substance containing asbestos as the plaintiffs in *Ingham* alleged or not.³⁷⁹

³⁷⁰ *Teen Vogue*, CONDÉ NAST, <https://www.condenast.com/brands/teen-vogue/> [<https://perma.cc/7QRU-8SUA>] (last visited Jan. 17, 2022) (describing audience as “3.4x more likely to be women 18-24”).

³⁷¹ See, e.g., Elizabeth, *supra* note 369; Kinonen, *supra* note 369.

³⁷² Margaux Anbouba, *The 2021 ELLE Green Beauty Stars*, ELLE (Apr. 6, 2021), <https://www.elle.com/beauty/a35905481/elle-green-beauty-stars-2021/> [<https://perma.cc/6SKB-A5S7>].

³⁷³ *Id.*

³⁷⁴ AMY SAUDNERS, *TOXIC BEAUTY* PRESS KIT 2 (2019), https://static1.squarespace.com/static/5d7fce8c65bd226016137907/t/5dc1a197e01d047541b841a8/1572970905297/Toxic+Beauty+Press+Kit_FINAL.pdf [<https://perma.cc/V445-UGGG>].

³⁷⁵ *On Glossy’s Anniversary, Fashion And Beauty Insiders Predict the Industries’ Next 5 Years*, GLOSSY (Apr. 30, 2021), <https://www.glossy.co/fashion/on-glossys-anniversary-fashion-and-beauty-insiders-predict-the-industries-next-5-years/> [<https://perma.cc/MV93-CGYJ>].

³⁷⁶ Flora, *supra* note 369.

³⁷⁷ For an examination of the history of beauty culture, see generally KATHY PEISS, *HOPE IN A JAR: THE MAKING OF AMERICA’S BEAUTY CULTURE* (1998) (explaining historical context of the beauty industry and its role in identity).

³⁷⁸ Press Release, Johnson & Johnson, Johnson & Johnson Consumer Health Announces Discontinuation of Talc-Based Johnson’s Baby Powder in U.S. and Canada (May 19, 2020), <https://www.jnj.com/our-company/johnson-johnson-consumer-health-announces-discontinuation-of-talc-based-johnsons-baby-powder-in-u-s-and-canada> [<https://perma.cc/LM89-8PE3>]; see also Martinne Geller & Lisa Girion, *Exclusive: Chanel, Revlon, L’Oreal Pivoting Away from Talc in Some Products*, REUTERS (June 9, 2020, 1:05 AM), <https://www.reuters.com/article/us-chanel-talc-powder-exclusive/exclusive-chanel-revlon-loreal-pivoting-away-from-talc-in-some-products-idUSKBN23G0GK> [<https://perma.cc/WD8F-UKHQ>].

³⁷⁹ Fifth Amended Petition, *supra* note 279, paras. 1-2, at 4.

In addition, some have raised questions about access to information and the role of corporate influence on science and regulation in the asbestos and talc contexts.³⁸⁰ The cosmetic-talc litigation provides an example of how litigation may help to bring product information to light. News sources have reported on company documents and other information from cosmetic-talc litigation,³⁸¹ and a number of the documents from the litigation have been made public.³⁸² Indeed, Johnson & Johnson has made a number of documents “that have been used as evidence in trials” available.³⁸³

CONCLUSION

The plaintiffs’ claims in *Ingham* provide a lens through which to view the cosmetic regulatory system, the healthcare system, and the tort system. Viewed through this lens, I argue that what emerges are three systems that suffer from substantial limitations when it comes to protecting—or in the case of healthcare, treating—women and people of color. However, even setting the claims in *Ingham* aside, the limitations of these systems are apparent.

Given the intersecting limitations of these systems, I contend that tort law can provide important benefits in the cosmetic context. Despite its limitations, tort law may complement and reinforce the regulatory system for cosmetics in ways that may be particularly important given the gendered nature of cosmetics and the relationship of these products with race. Tort law may provide redress and compensation to people injured by cosmetics, encourage members of the cosmetic industry to take due care, and bring to light information, including about cosmetic safety, that can inform cosmetic regulation. Accordingly, state tort law claims in the cosmetic context should not be preempted. Cosmetic reform is greatly needed as the current regulatory system fails to adequately protect the health and safety of those who use cosmetics, but in enacting cosmetic reform, Congress should preserve state tort law claims. Preempting

³⁸⁰ See, e.g., David Eligman, Tess Bird & Caroline Lee, *Dust Diseases and the Legacy of Corporate Manipulation of Science and Law*, 20 INT’L J. OCCUPATIONAL & ENV’T HEALTH 115, 115 (2014); Triet H. Tran, Joan E. Steffen, Kate M. Clancy, Tess Bird & David S. Egilman, *Talc, Asbestos, and Epidemiology: Corporate Influence and Scientific Incognizance*, 30 EPIDEMIOLOGY 783, 783 (2019).

³⁸¹ See, e.g., Girion, *supra* note 214; Kirkham & Girion, *supra* note 325; Roni Caryn Rabin & Tiffany Hsu, *Baby Powder, A Carcinogen, and Red Flags*, N.Y. TIMES, Dec. 15, 2018, at A1, A22.

³⁸² See, e.g., DOCUMENTCLOUD, <https://www.documentcloud.org/app?q=%2Bproject%3Ajohnson-johnson-40934> (search results for “+project:johnson-johnson-40934”) (last visited Jan. 17, 2022) (containing documents cited in Girion, *supra* note 214); BROWN UNIV. LIBR. DIGIT. REPOSITORY, <https://repository.library.brown.edu/studio/search/?q=David+Egilman+Papers> (search results for “David Egilman Papers”) (last visited Jan. 17, 2022).

³⁸³ Johnson & Johnson, *Disclaimer*, BOX, <https://jjcloud.ent.box.com/s/2x692lcj24crvjunf0lnu590zw5g528e/file/358022398021> (last visited Jan. 17, 2022); see also Johnson & Johnson, *Facts About Talc*, BOX, <https://jjcloud.ent.box.com/s/2x692lcj24crvjunf0lnu590zw5g528e> (last visited Jan. 17, 2022) (providing Johnson & Johnson documents related to talc litigations).

such claims may disproportionately impact women, including women who are members of other historically excluded groups, and may ultimately make cosmetics less safe for all.