FRENCH-TIPPED FORMALDEHYDE: WHY FDA'S STATUTORY FRAMEWORK ENABLES TOXIC CHEMICAL EXPOSURES IN MANICURE PRODUCTS; HOW RULEMAKING OR CONGRESSIONAL ACTION CAN CURB ITS DETRIMENTAL EFFECT ON OCCUPATIONAL HEALTH

ANH-THI LE*

* J.D. Candidate, 2024, American University Washington College of Law. I would be nothing without my family, my friends, and their unconditional support and encouragement. To the *Administrative Law Review* staff, thank for your commitment and invaluable editorial guidance. This Comment is lovingly dedicated to my parents, and especially to my mother, who has labored tirelessly as a nail technician for over twenty years. Because of your unwavering resilience and sacrifice, I can pursue my dreams, and for that, I am endlessly inspired and grateful—cảm ơn bố mẹ cho tất cả.

INTRODUCTION

In the 1970s, a prominent actress sought to aid the resettlement of Vietnamese refugees by running a vocational training program, spurring a "butterfly effect" that would create the modern American nail salon.[1] People who immigrated from Vietnam—beginning with the twenty women who received the actress's manicure training—gradually and significantly transformed the nail salon industry.[2] What once was an unaffordable and unattainable experience available only to elites blossomed into an "affordable luxury" for many Americans.[3] As manicures, pedicures, and other nail design services become increasingly popular, customer demands continue to bolster the booming industry; in fact, between 2014 and 2019, the number of U.S. nail salons doubled.[4] Even with strict government-imposed health and safety precautions at the height of the COVID-19 pandemic, nail salons have successfully rebounded to meet customer

1. *See* Regan Morris, *How Tippi Hedren Made Vietnamese Refugees into Nail Salon Magnates*, BBC NEWS (May 3, 2015), https://www.bbc.com/news/magazine-32544343 (detailing how a beauty training at a Vietnamese refugee camp led to the nail salon industry's growth).

2. *See id.*

3. *See id.* (noting that nail services were "out of reach for most American women" prior to Vietnamese immigrants joining the industry); Stanislava Ilic-Godfrey, *Recovering from the Pandemic: A Bright Outlook for the Personal Care Service Industry*, U.S. BUREAU LAB. STAT.: BEYOND THE NOS. (May 20, 2022), https://www.bls.gov/opub/btn/volume-11/recovering-from-the-pandemic-a-bright-outlook-for-the-personal-care-service-industry.htm (stating that many consumers view nail salon services as an "affordable luxury").

4. *See* Ilic-Godfrey, *supra* note 3 (stating that growing demand derives from "social media and celebrities' popularization of various nail shapes, extensions, artsy designs, and coloring, which are more complex than basic manicures and pedicures"); Press Release, Research and Markets, United States Nail Salons Market 2021: Demand Still Strong for Affordable Luxury (Sept. 29, 2021) [hereinafter Nail Salon Market Report], www.prnewswire.com/news-releases/united-states-nail-salons-market-2021-demand-still-strong-for-affordable-luxury-301387697.html (noting that the number of U.S. nail salons in 2019 increased 50% from just five years earlier).

demands.[5] Today, the brick-and-mortar nail salon industry is worth over $8 billion and is expected to continue to grow over the next decade.[6]

But behind this veil of prosperity, nail salon technicians face occupational hazards from the nail products that they must use in the scope of their work.[7] These products can contain dozens of chemical vapors.[8] The effects of these harmful vapors are magnified by their day-to-day use for long hours in salon.[9] As a result, nail technicians experience chemical exposure intensities 1,200 times that of the average American.[10] They inhale ten times more flame-retardant and plasticizer chemicals than the average electronic-waste facility employee.[11] Levels of cancer-causing chemicals in nail salons can even exceed those in auto garages.[12] For many nail technicians, these chemical exposures manifest in short-term dermal and respiratory irritation.[13] For others—including still unknown future victims—exposures manifest as long-term debilitating health outcomes like cancer, asthma, and reproductive issues.[14] Today, Vietnamese-American nail technicians—the

5. *See* Nail Salon Market Report, *supra* note 4 (observing the nail salon industry's recovery from a halt in growth during the COVID-19 pandemic).

6. *See id.*; Ilic-Godfrey, *supra* note 3.

7. *See* Grace X. Ma, Zhengyu Wei, Rosy Husni, Phuong Do, Kathy Zhou, Joanne Rhee et al., *Characterizing Occupational Health Risks and Chemical Exposures Among Asian Nail Salon Workers on the East Coast of the United States*, 44 J. CMTY. HEALTH 1168, 1177 (2019), https://doi.org/10.1007/s10900-019-00702-0 (finding that "hazardous chemicals contained in nail care products are the fundamental source and risk for chemical exposures to nail salon workers").

8. *See Health Hazards in Nail Salons*, U.S. OCCUPATIONAL SAFETY & HEALTH ADMIN., https://www.osha.gov/nail-salons/chemical-hazards (last visited May 9, 2023) (providing that "[w]orking in a nail salon exposes workers to many different chemicals each day" and that the "exposures can 'add up'" when many products are used at the same time on a daily basis).

9. *Id.*

10. *See* Kelsey-anne Fung, *Gel, Acrylic, or Shellac: The Impact of Southeast and East Asian Immigrant Nail Salon Workers on the Health Care System*, 14 U. MD. L.J. RACE, RELIG., GENDER & CLASS 121, 123 (2014).

11. *See* Anuradha Varanasi, *Nail Salon Technicians Inhale 10 Times More Chemicals Than E-Waste Workers*, FORBES (Feb. 13, 2022), https://www.forbes.com/sites/anuradhavaranasi/2022/02/13/nail-salon-workers-are-exposed-to-10-times-higher-chemicals-than-e-waste-workers/?sh=6d636bf49ea2.

12. *See* Victoria Forster, *Levels of Some Cancer-Causing Chemicals in Nail Salons Higher Than in Auto Garages Says New Study*, FORBES (May 8, 2019, 8:20 AM), https://www.forbes.com/sites/victoriaforster/2019/05/08/levels-of-cancer-causing-chemicals-in-nail-salons-higher-than-in-auto-garages/.

13. *See Health Hazards in Nail Salons*, *supra* note 8 (providing examples of potentially hazardous chemicals in nail salons and side effects such as headaches, dizziness, irritation, nausea, and exhaustion).

14. *See* PREETI SHARMA, SABA WAHEED, VINA NGUYEN, LINA STEPICK, REYNA

same population credited for forging the modern, archetypal American nail salon—experience up to twice the level of phthalates (reproductive toxicants) in their bodies compared to the general Asian-American population.[15] The modern nail salon industry suffers from an "epidemic of health issues" caused by chemical exposures.[16] The risks from those exposures are exacerbated because this workforce is largely comprised of women of Asian descent who immigrated to the United States with limited English-speaking proficiency and who experience a lack of access to "culturally and linguistically appropriate educational and outreach materials."[17]

Yet despite these risks, the industry continues to thrive.[18] For many nail technicians, these exposures are just part of earning a living in an industry that appeals to their unique employment needs.[19] Further, the nail salon industry comes with its own set of exploitative practices.[20] Nail technicians are "frequently underpaid, overworked, and misclassified as independent contractors instead of employees."[21] Without the safety net of labor

---

ORELLANA, LIANA KATZ, ET AL., UCLA LAB. CTR., NAIL FILES: A STUDY OF NAIL SALON WORKERS AND INDUSTRY IN THE UNITED STATES 32, 34 (2018) ("Nail salon workers are at risk for many different short- and long-term occupational health conditions, ranging from respiratory disorders to cancer, that are related to the products they work with.").

15. *See* Morris, *supra* note 1 (discussing how Vietnamese-Americans transformed nail salons); Julia R. Varshavsky, Rachel Morello-Frosch, Suhash Harwani, Martin Snider, Syrago-Styliani E. Petropoulou, June-Soo Park, et al., *A Pilot Biomonitoring Study of Cumulative Phthalates Exposure among Vietnamese American Nail Salon Workers*, INT'L J. ENV'T RSCH. & PUB. HEALTH, Jan. 2, 2020, at 2, 10, https://doi.org/10.3390/ijerph17010325 (recognizing that Vietnamese-Americans are a "uniquely vulnerable occupational group" to phthalate exposure in nail salons as this group makes up "just over half" of the U.S. nail salon workforce).

16. *See* ASS'N OF ASIAN PAC. CMTY. HEALTH ORGS., ADDRESSING NAIL SALON WORKER PATIENT HEALTH 4, 6 (2016), https://aapcho.org/wp/wp-content/uploads/2017/01/Nail-Salon-Worker-Health-Center-Toolkit.pdf.

17. *See id.*

18. *See* Ilic-Godfrey, *supra* note 3 (noting that the booming nail salon industry will see fast employment growth for technicians over the next decade).

19. *See* Jin Young Seo, Ying-Yu Chao, Ka Man Yeung & Sheila M. Strauss, *Factors Influencing Health Service Utilization Among Asian Immigrant Nail Salon Workers in the Greater New York City Area*, 44 J. CMTY. HEALTH 1, 1–2 (2019), https://doi.org/10.1007/s10900-018-0544-7 (finding that "Asian immigrant women in the [United States] are attracted to a career in nail salons because the training required to become a licensed professional is minimal and inexpensive, and they can work with limited English proficiency").

20. *See* Sarah Maslin, *The Price of Nice Nails*, N.Y. TIMES (May 7, 2015), https://www.nytimes.com/2015/05/10/nyregion/at-nail-salons-in-nyc-manicurists-are-underpaid-and-unprotected.html (highlighting how manicurists are routinely underpaid and exploited).

21. Press Release, Phil Ting, Cal. State Assemb., California State Assembly Passes Ting Bill to Protect Nail Salon Workers (May 22, 2016), https://a19.asmdc.org/press-

protections, nail technicians face barriers to issuing formal complaints and filing workers' compensation claims over safety hazards in the workplace.[22]

Occupational safeguards fall short of protecting nail technicians. While the Occupational Safety and Health Administration (OSHA) sets "permissible exposure limits" for chemical air contaminants found in nail salons, OSHA has recognized that the limits "are outdated and inadequate for ensuring protection of worker health."[23] Additionally, although OSHA recommends against using products that contain harmful chemicals in the workplace, it does not restrict nail salons from using products containing these ingredients.[24] Ultimately, occupational guidance and regulations shift the burden of worker safety onto private nail salons, ninety percent of which are small businesses without designated safety personnel.[25] This demonstrates a need for regulatory action at the source: the manicure products themselves. However, the level of cosmetic product oversight is grossly incongruent with the cosmetic industry's success.[26]

In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA) after years of industry resistance.[27] In doing so, Congress intended to replace the 1906 Pure Food and Drug Act and, for the first time, enable federal oversight of cosmetics to safeguard consumers from dangerous beauty

---

releases/20160523-assembly-passes-ting-bill-protect-nail-salon-workers.

22. *See* ZOË WEST, RUSSELL WEAVER & KC WAGNER, UNVARNISHED: PRECARITY AND POOR WORKING CONDITIONS FOR NAIL SALON WORKERS IN NEW YORK STATE, CORNELL SCH. INDUS. & LAB. RELS., WORKER INST. 7, 14 (2022), https://hdl.handle.net/1813/111162 (noting that nail salon employer noncompliance with labor and wage laws deprives technicians of protections like workers' compensation and contributes to health issues in the industry).

23. *Permissible Exposure Limits – Annotated Tables*, U.S. OCCUPATIONAL SAFETY & HEALTH ADMIN., https://www.osha.gov/annotated-pels (last visited May 9, 2023); *see* SHARMA ET AL., *supra* note 14, at 47 (noting that some permissible exposure limits for chemicals commonly used in nail salons have not been updated since the 1970s).

24. *See Health Hazards in Nail Salons*, *supra* note 8.

25. *See* Lupita D. Montoya & Aaron Lamplugh, *Nail Salon Workers Face Respiratory Illness and Cancer Risks, Study Shows*, TRUTHOUT (Dec. 8, 2019), https://truthout.org/articles/nail-salon-workers-face-respiratory-illness-and-cancer-risks-study-shows/; *see also* SHARMA ET AL., *supra* note 14, at 47 (finding that many nail technicians are not trained to handle chemicals safely).

26. *See* Aaron Kaufmann, Brianna Rauenzahn & Jamison Chung, *Does Cosmetics Regulation Need a Makeover?*, REGUL. REV. (May 1, 2021), https://www.theregreview.org/2021/05/01/saturday-seminar-does-cosmetic-regulation-need-makeover/ (noting that while the cosmetics industry rakes in about $70 billion annually, the Food and Drug Administration's (FDA's) Office of Cosmetics and Colors has fewer than thirty staff members to monitor and regulate cosmetics).

27. *See* Kat Eschner, *Three Horrifying Pre-FDA Cosmetics*, SMITHSONIAN MAG. (June 26, 2017), https://www.smithsonianmag.com/smart-news/three-horrifying-pre-fda-cosmetics-180963775/ (providing that prior to the Federal Food, Drug, and Cosmetic Act's (FDCA's) passage, manufacturers enjoyed seeing their products "flourish[] totally unchecked").

products.[28] But the cosmetics regime soon proved to be insufficient in reining in dangerous products, and, over the next several decades, industry players successfully quashed numerous attempts to reform cosmetic ingredient safety.[29] The cosmetics industry continues to reap the benefits of a weak regulatory landscape: since the 1970s, the industry has funded and controlled the "only panel tasked with determining the safety of individual cosmetic ingredients."[30] The industry's self-regulation reveals a dismal truth for both consumers and salon workers: despite the beauty industry's increasing use of chemicals in cosmetics, manufacturers today are still not subject to any Food and Drug Administration (FDA) pre-market ingredient review or approval.[31]

Despite a recent legislative overhaul of the FDCA that altered the cosmetic regime for the first time in over eighty years, FDA still lacks the authority it needs to restrict the use of harmful chemicals in nail products.[32] As studies of long-term

---

28. *See How Did the Federal Food, Drug, and Cosmetic Act Come About?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fda-basics/how-did-federal-food-drug-and-cosmetic-act-come-about (Mar. 28, 2018).

29. *See* Editorial Board, *Do You Know What's in Your Cosmetics?*, N.Y. TIMES (Feb. 9, 2019), https://www.nytimes.com/2019/02/09/opinion/cosmetics-safety-makeup.html [hereinafter *Do You Know What's in Your Cosmetics?*] (describing "a rash of health and safety problems" in cosmetics in the 1980s including how cosmetic trade lobbyists have "spent years quashing efforts to close . . . gaps in regulatory oversight").

30. *See* Taylor L. Kraus, Note, *Caring About Personal Care Products: Regulation in The United States, The European Union, and China in the Age of Global Consumption*, 33 WIS. INT'L L.J. 167, 177 (2014) (detailing how "[i]n 1973, the cosmetic and personal care industry agreed to implement self-regulation in order to avoid changes in legislation as part of a lobbying deal with Congress" and "implemented self-regulation by forming the [Cosmetic Ingredient Review Panel (CIR)]"); *Do You Know What's in Your Cosmetics?*, *supra* note 29.

31. *See Cosmetic Chemicals Market to Nearly Grow Two-Fold Amid Rising Preference for Eco-Friendly Cosmetic Products*, CISION: PR NEWSWIRE (Oct. 3, 2022, 11:30 AM), https://www.prnewswire.com/news-releases/cosmetic-chemicals-market-to-reach-us-22-billion-by-2032-as-demand-for-organic-hair--skin-care-products-rises-by-5-301639080.html (projecting the cosmetic chemicals industry will grow by 5.8 % over the next decade); NIKKI REEVES, GENEVIÈVE MICHAUX, LISA M. DWYER, JESSICA RINGEL, EVA A. TEMKIN, CHRISTINA M. MARKUS ET AL., KING & SPALDING, NEARLY A CENTURY IN THE MAKING: CONGRESS MODERNIZES FDA'S REGULATION OF COSMETICS 1 (2023) [hereinafter FDA MODERNIZATION], https://www.kslaw.com/attachments/000/010/269/original/Nearly_a_Century_in_the_Making_-_Congress_Modernizes_FDA%E2%80%99s_Regulation_of_Cosmetics.pdf (providing that while the Modernization of Cosmetics Regulations Act of 2022 (MOCRA) is the first significant expansion to FDA's cosmetic authority since 1938, the bill stops short of imposing a pre-market FDA review or approval process).

32. Tracey Gonzalez, *FDA Significantly Reforms Cosmetics Regulations for First Time in Over 80 Years*; EPSTEIN BECKER GREEN (Feb. 3, 2023), https://www.ebglaw.com/insights/fda-significantly-reforms-cosmetics-regulations-for-first-time-in-over-80-years/; *see* Bryant M.

effects of chemical exposures in the nail salon workplace remain few and far between, workplace protections continue to be underregulated; legislation and regulations must address manicure product safety to ensure that this vulnerable group is able to prevent debilitating health effects before it is too late.[33]

Part I of this Comment examines the most pervasive nail product chemicals and their potential effects on occupational health. Part II evaluates how FDA's rigid cosmetic framework limits the agency's pre-and post-market authority and prevents it from addressing nail product safety issues through traditional enforcement powers. Part III analyzes the permissible extent of FDA rulemaking on nail salon product chemicals. Part IV analyzes how current trends in jurisprudence may affect FDA's authority to protect professionals (rather than just consumers alone) from harmful chemicals in nail products. Part V examines recent cosmetic reform and discusses provisions necessary to protect nail technicians through ingredient review, using an Environmental Protection Agency (EPA) chemical ingredient reform as a blueprint. Part VI recommends two possible remedies through either legislative action or FDA rulemaking.

I. TOXIC CHEMICALS, POISONED WORKERS

A. Toxic Chemicals

Each day at work, nail technicians can encounter dozens of chemical constituents in the products necessary to perform their jobs.[34] The most notorious example of harmful nail product ingredients is the "toxic trio," a

---

Godfrey & Tina Papagiannopoulos, *Congress Adds Some Teeth to FDA's Authority to Regulate Cosmetics*, FOLEY HOAG (Jan. 18, 2023), https://www.foleyhoag.com/news-and-insights/publications/alerts-and-updates/2023/january/congress-adds-some-teeth-to-fdas-authority-to-regulate-cosmetics/ (noting that even with the passage of MOCRA, cosmetics manufacturers still do not need to undergo any pre-market ingredient notification or receive review or approval from FDA); Michelle Chen, *90 Percent of the Over 10,000 Chemicals in Nail Products Haven't Been Evaluated For Safety*, NATION: SCI. & HEALTH BLOG (May 15, 2015), https://www.thenation.com/article/archive/90-percent-over-10000-chemicals-nail-products-havent-been-evaluated-safety/ (asserting that without pre-market approval of cosmetic products, dangerous substances are presumed to be safe, resulting in "profound" environmental and reproductive justice implications for nail technicians).

33. *See infra* Part I.A (discussing potential illnesses associated with exposure to common nail product chemicals and the shortage of scientific studies that examine adverse health outcomes in nail technicians); Chen, *supra* note 32 ("We don't believe that state or federal agencies . . . should wait until we have body counts of how many people have died from cancer . . . before there is reform made.").

34. *See* N.Y. DEP'T OF HEALTH, REVIEW OF CHEMICALS USED IN NAIL SALONS 6 (2016), https://www.health.ny.gov/press/reports/docs/nail_salon_chemical_report.pdf.

combination of dibutyl phthalate, formaldehyde, and toluene.[35] Like many other chemicals in nail care products, components of the toxic trio have been linked to a variety of negative health outcomes through inhalation and dermal contact.[36] Formaldehyde is a nail polish hardening agent that causes difficulty breathing along with skin, eye, and nose irritation.[37] Formaldehyde is also a known human carcinogen.[38] The FDA-supported, industry-operated Cosmetic Ingredient Review (CIR) panel concluded in 2012 that formaldehyde is "safe in the present practices of use and concentration in nail hardening products," despite acknowledging that at "high doses" formaldehyde can cause nasopharyngeal cancers—the report ignored potential long-term accumulations that technicians may experience.[39]

Dibutyl phthalate (DBP) is a nail polish bonder that, in the short term, causes nausea and skin, eye, and nose irritation.[40] In the long term, DBP is a reproductive toxin linked to birth defects and endocrine disruption in animals.[41] However, based on research last updated in 2002, FDA did not find a "sound, scientific basis to support taking regulatory action against cosmetics containing phthalates."[42]

---

35. *See* Seo et al., *supra* note 19, at 2 (referring to the "toxic trio" as "main ingredients" of nail products).

36. *See Health Hazards in Nail Salons*, *supra* note 8 (listing hazardous chemicals found in nail salons and their effects).

37. *Id.*

38. AM. CANCER SOC'Y, KNOWN AND PROBABLE HUMAN CARCINOGENS 4 (2022) https://www.cancer.org/content/dam/CRC/PDF/Public/633.00.pdf.

39. *See* IVAN J. BOYER & BART A. HELDRETH, FINAL AMENDED REPORT: FORMALDEHYDE AND METHYLENE GLYCOL 17–18 (2011), https://www.alegesanatos.ro/dbimg/files/Formaldehyde%20-%20Methylene%20Glycol.pdf (noting that the CIR panel concluded formaldehyde was safe in nail hardening products after considering data from industry groups such as the Nail Manufacturers Council and the Personal Care Products Council); *id.* at 14–15 (utilizing a study that measured formaldehyde concentrations in nail salons over an eight-hour period); *Health Hazards in Nail Salons*, *supra* note 8 (noting that exposures "add up" when used "day after day"); *see also* Lauren Jacobs, *Beauty Shouldn't Cause Pain: A Makeover Proposal for the FDA's Cosmetics Regulation*, 39 J. NAT'L ASS'N ADMIN. L. JUDICIARY 82, 105 (2019) (noting that FDA "authorized the cosmetics industry to police itself" by supporting the CIR panel, which was established by the Personal Care Products Council, an industry trade association).

40. *See Health Hazards in Nail Salons*, *supra* note 8.

41. *See* CAL. DEP'T OF TOXIC SUBSTANCES CONTROL, POTENTIAL HEALTH AND SAFETY IMPACTS OF CHEMICALS IN NAIL PRODUCTS (2016) [hereinafter POTENTIAL HEALTH & SAFETY IMPACTS], https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/04/DTSC-Work-Plan-Implementation-Potential-Health-and-Safety-Impacts-of-Chemicals-in-Nail-Products-11-15-16.pdf.

42. *See Phthalates in Cosmetics*, U.S. FOOD & DRUG ADMIN. (May 19, 2022), https://www.fda.gov/cosmetics/cosmetic-ingredients/phthalates-cosmetics.

Toluene is an organic solvent added to nail polish for a smoother application.[43] Toluene has also been linked to spontaneous miscarriages in occupationally-exposed women.[44] The CIR panel last reviewed toluene in 2005, finding that "adverse effects occurred only at levels many times higher than those observed when people used nail polish."[45] The CIR panel did not consider toluene's effects at levels that nail technicians experience—instead, it concluded that "high exposures . . . are not relevant to the use of toluene in cosmetic products."[46]

In attempts to market their products as "3-free," some manufacturers substitute out the toxic trio for chemicals such as triphenyl phosphate (TPHP) and didiethylhexyl phthalate (DEHP).[47] TPHP, a plasticizer and flame-retardant commonly substituted for DBP, has been linked to reproductive toxicity and endocrine disruption.[48] DEHP, a chemical banned in the European Union, is a hormone disrupter and possible carcinogen.[49]

Overall, few studies examine nail product chemical exposures and adverse health outcomes in nail technicians, resulting in limited scientific research on the subject.[50] The shortage is partially due to a diversity problem: members of nail technicians' ethnic and cultural community are not well-represented in the research community, so "the people who care about [nail technicians] most [are not] . . . involved in addressing the

---

43. *See* POTENTIAL HEALTH & SAFETY IMPACTS, *supra* note 41.

44. *See* U.S. ENV'T PROT. AGENCY, TOLUENE 108–88–3 (2016), https://www.epa.gov/sites/default/files/2016-09/documents/toluene.pdf (noting that "increased incidence of spontaneous abortions was . . . reported among occupationally exposed women"). *But see id.* (noting that such links are inconclusive due to confounding variables and a low number of evaluated cases).

45. *See Nail Care Products*, U.S. FOOD & DRUG ADMIN. (Feb. 25, 2022), https://www.fda.gov/cosmetics/cosmetic-products/nail-care-products.

46. *See Annual Review of Cosmetic Ingredient Safety Assessments—2004/2005*, 25 INT'L J. TOXICOLOGY, Mar. 2006 Supp. 2, at 1, 79, https://doi.org/10.1080/10915810600964618.

47. *See* Carolyn Crist, *Nail Polishes Often Claim Falsely to be Toxin-Free*, REUTERS (Oct. 10, 2018), https://www.reuters.com/article/us-health-nailpolish/nail-polishes-often-claim-falsely-to-be-toxin-free-idUSKCN1MK2SJ. Some refer to triphenyl phosphate as TPHP and others refer to it as TPP; this Comment will use "TPHP" when discussing triphenyl phosphate. *Compare id.* (referring to triphenyl phosphate as TPHP), *with* POTENTIAL HEALTH & SAFETY IMPACTS, *supra* note 41 (referring to triphenyl phosphate as TPP).

48. *See* Anna Young, *The Continual Regrettable Substitution of Nail Polish Ingredients*, HARV. T.H. CHAN SCH. PUB. HEALTH (Feb. 22, 2017), https://www.hsph.harvard.edu/hoffman-program/2017/02/22/the-continual-regrettable-substitution-of-nail-polish-ingredients/; Crist, *supra* note 47.

49. *See id.*

50. *See* SHARMA ET AL., *supra* note 14, at 32 (noting "there have been limited studies on the combined and long-term health effects" of chemicals in nail salon products).

problems."[51] The shortage of studies fails to reflect the serious concerns nail technicians have relating to the negative health outcomes associated with exposures to chemicals in nail products.[52]

B. Poisoned Workers

In 1988, Le Thi Lam immigrated to the United States from Vietnam.[53] Soon after becoming a nail technician, she developed asthma and a thyroid condition.[54] Ailing and concerned about the chemical exposures from nail products, Lam left the nail salon industry, but she returned after failing to find another job.[55] Years later, she learned that she had breast cancer.[56]

After immigrating to New York from Nepal, Pabitra Dash became a nail technician.[57] Her relatives told her that "for immigrants like [them], working in a nail salon was the best choice."[58] Dash worked in the nail salon for years, where she inhaled chemicals such as toluene and formaldehyde.[59] She just "wanted to survive and eventually start a family"—instead, over the course of ten years, Dash suffered seven miscarriages.[60]

Dr. Charles Hwu, an internist in Flushing, New York, routinely encounters a particular set of conditions affecting otherwise healthy young women:

> They come in usually with breathing problems, some symptoms similar to an allergy, and also asthma symptoms—they cannot breathe . . . . Judging from the symptoms with these women, it seems that they are either smokers, secondhand smokers or asthma patients, but they are none of the above. They work for nail salons.[61]

---

51. *See* Forster, *supra* note 12 (noting that due to workers' fears, data collection from nail salons "requires tremendous sensitivity and a respectful approach to the communities being served").

52. *See* Sarah Maslin Nir, *Perfect Nails, Poisoned Workers*, N.Y. TIMES (May 15, 2015), https://www.nytimes.com/2015/05/11/nyregion/nail-salon-workers-in-nyc-face-hazardous-chemicals.html (profiling nail technicians and the health effects they experienced after years of salon exposures).

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

57. *See* Pabitra Dash, Opinion, *My Job and My Seven Miscarriages: Nail Salon Workers Need More Protections Now*, N.Y. DAILY NEWS (May 11, 2022, 11:00 AM), https://www.nydailynews.com/opinion/ny-oped-miscarriages-work-nail-salon-chemicals-20220511-eucsvslqyrfupatkcmbqwnj6ha-story.html.

58. *Id.*

59. *Id.*

60. *Id.*

61. Maslin Nir, *supra* note 52.

These stories are not unique, and these women are not alone. The limited medical studies that do exist illustrate a pervasive set of ailments distinctive to nail product chemical exposures, often finding that nail technicians suffer from respiratory, skin, and musculoskeletal issues as a result of exposure to the "laundry list" of chemicals they encounter daily.[62]

Beyond the short-term ailments, studies hint at more insidious illnesses emerging from long-term exposure.[63] Over a twenty-year exposure to manicure products nail technicians are over one hundred times more likely to develop leukemia due to formaldehyde exposures and are up to thirty-eight times more likely to develop mouth and throat cancer due to benzene exposures.[64] By contrast, it is highly unlikely that nail salon customers will face exposure to a significant or harmful concentration of manicure product chemicals—after all, consumers only spend a fraction of the time in nail salons that technicians do.[65] Therefore, special product safety considerations are needed to account for the exposure levels that nail technicians face.

II. TRADITIONAL POWERS UNDER FDA'S RIGID COSMETIC FRAMEWORK

A. FDA's Limits to Pre-Market Evaluation

FDA does not possess the requisite pre-market authority to regulate chemicals in nail care products.[66] Unlike under the FDCA's drug, device, or additive approval processes, manufacturers do not need ingredient approval from FDA before distributing cosmetics in interstate commerce.[67] Rather, the cosmetics industry itself is responsible for pre-market safety assessment

62. *See* Dina Fine Maron, *These 4 Chemicals May Pose the Most Risk for Nail Salon Workers*, SCI. AM. (May 12, 2015), https://www.scientificamerican.com/article/these-4-chemicals-may-pose-the-most-risk-for-nail-salon-workers/.

63. *See* Forster, *supra* note 12 (finding nail technicians face a higher risk of developing certain cancers).

64. *See id.*

65. *See id.*

66. *See* Fung, *supra* note 10, at 125–26 (noting FDA's lack of authority to review and arguing that Congress "improperly delegated" ingredient review to the politically powerful cosmetic industry, which in turn acts through loopholes that compromise nail technician health).

67. *See* Jaina Patel, Note, *Amending the Food, Drug, and Cosmetic Act's Labeling Requirements for Cosmetics*, 90 GEO. WASH. L. REV. ARGUENDO 31, 34 (2022) (noting that the FDCA's regulation of cosmetics "is not nearly as robust as it is for other FDA-regulated products"); Morgan G. Egeberg, Note, *Beauty is Pain: An Analytical View of the American Beauty Industry and the Effects of Regulation on Consumers*, 23 QUINNIPIAC HEALTH L.J. 303, 314 (2022) (stating "the [FDCA] includes one hundred and twelve pages of food and drug regulation, but only two pages for cosmetics").

through the CIR panel, an industry-funded mechanism that examines voluntary, manufacturer-provided data to make non-binding conclusions regarding product safety.[68] Since its inception in 1976, the CIR panel has only analyzed eleven to thirteen percent of all cosmetic ingredients and has only found eleven unsafe chemicals out of the 10,000 used in cosmetics.[69] Additionally, some believe the industry-funded findings pose a conflict of interest and question the impartiality of the CIR panel.[70] This ambivalence toward current ingredient safety determinations demonstrates a need for FDA to obtain its own independent ingredient review authority.

FDA could improve pre-market product safety but has failed to define testing or evidence requirements for safety substantiations.[71] Under FDA's regulations, ingredients in cosmetic products "shall be adequately substantiated for safety prior to marketing" or otherwise bear a warning label stating that "the safety of this product has not been determined."[72] FDA directs manufacturers to rely on "available toxicological test data" or conduct tests to assess ingredients and formulae for safety, but does not specify exactly what records manufacturers must provide to show such substantiation.[73] As

68. *See* Jacobs, *supra* note 39, at 124.

69. *See* 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, 88 (2017).

70. *See Do You Know What's in Your Cosmetics?*, *supra* note 29 (noting that "some of the panel's conclusions have been at odds with those of impartial government entities like the National Toxicology Program").

71. *See* HASSAN Z. SHEIKH & AGATA BODIE, CONG. RSCH. SERV., R42594, FDA REGULATION OF COSMETICS AND PERSONAL CARE PRODUCTS 11–12 (2022).

72. 21 C.F.R. § 740.10(a) (2022). *But see* Devon Wm. Hill, Frederick A. Stearns, Sara M. Gaines & Ryan D'Souza, *Cosmetics Regulations Get a Makeover: Congress Enacts New Requirements*, NAT'L L. REV. (Jan. 10, 2023), https://www.natlawreview.com/article/cosmetics-regulations-get-makeover-congress-enacts-new-requirements (noting that while existing regulations allow a cosmetic product without adequate substantiation of safety to still be marketed so long as it bears the statement, once new adulteration provisions under MOCRA go into effect, "this option to label inadequately-substantiated cosmetic products will no longer be available.").

73. *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, But Are FDA-Regulated*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated (Mar. 2, 2022) ("[T]he safety of a product can be adequately substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic, and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information."(citing Food, Drug, and Cosmetic Products: Warning Statements, 40 Fed. Reg. 8,912, 8,916 (Mar. 3, 1975))); *see also Letter: Cosmetics With Banned and Unsafe Ingredients*, ENV'T WORKING GRP. (Sept. 26, 2007), https://www.ewg.org/news-insights/official-correspondence/cosmetics-banned-and-unsafe-ingredients (recommending that FDA set a safety standard for cosmetics by

long as a scientist can "reasonably conclude" that the product is not harmful through its intended use or foreseeable misuse, manufacturers can market the product without the prescribed warning label, regardless of the kind of tests conducted or data provided.[74] Cosmetic manufacturers are not required to provide specific research to demonstrate ingredient safety or share their safety information with FDA before distributing their products in commerce.[75]

Recent developments could scale back FDA's already limited pre-market oversight of cosmetics. In December 2022, Congress passed the Modernization of Cosmetics Regulations Act of 2022 (MOCRA) as part of the Consolidated Appropriations Act of 2023.[76] MOCRA requires manufacturers to ensure there is "adequate substantiation of safety" of their cometic products.[77] MOCRA defines an "adequate substantiation of safety" as tests or evidence that qualified scientific experts would believe are sufficient to support a "reasonable certainty" that a cosmetic product is safe under its "customary or usual" conditions of use.[78]

Like existing FDA regulations, MOCRA does not specify the standards for tests that manufacturers must maintain or conduct to demonstrate safety.[79] Rather, by providing that manufacturers need only demonstrate cosmetic safety under "customary or usual" usages—despite current FDA regulations requiring the additional consideration of "reasonably expected related uses"—MOCRA codifies an even weaker safety expectation for

---

clarifying the current regulatory requirement of "adequate substantiation of safety").

74. *See* U.S. FOOD & DRUG ADMIN., COSMETICS LABELING GUIDE 15–16, https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide (Feb. 25, 2022).

75. *See* Justice Tecson, Comment, *Total Makeover: Federal Cosmetics Regulation and Its Need for Legislative Overhaul to Ensure Consumer Protection*, 51 GOLDEN GATE U. L. REV. 127, 134 (2021) (noting that while cosmetic manufacturers have a legal duty to substantiate product safety, FDA cannot mandate specific safety testing methods).

76. Consolidated Appropriations Act of 2023, Pub. L. 117-328, §§ 3501–08. At the time of this writing, the Government Printing Office (GPO) has not published the Consolidated Appropriations Act of 2023. This Comment's use of "MOCRA" means MOCRA's location in the Appropriations Act, §§ 3501–08.

77. *Id.* sec. 3502, § 608(a) (to be codified in scattered sections of 21 U.S.C.).

78. *Id. s*ec. 3502, § 608(c)(1)–(2) (to be codified in scattered sections of 21 U.S.C.).

79. *See* SHEIKH & BODIE, *supra* note 71, at 11–12 ("FDA regulations do not specify how cosmetic products and their ingredients are to be tested."); JENNIFER M. GOMEZ, KATHERINE L. RAYMOND, JAMES C. FRASER, NILDA M. ISIDRO, SYLVIA E. SIMSON & SARA K. THOMPSON, POTENTIAL LITIGATION IMPACTS OF THE MODERNIZATION OF COSMETICS REGULATION ACT OF 2022, GREENBERG TRAURIG 3 (Dec. 2022), https://www.gtlaw.com/-/media/files/insights/alerts/2022/12/gt-alert_potential-litigation-impacts-of-the-modernization-of-cosmetics-regulation-act-of-2022.pdf ("The bottom line as to Section 608 is that FDA's standard for what is 'safe' and what constitutes sufficient substantiation of safety both leave a fair amount of discretion to manufacturers conducting the safety testing . . . .").

cosmetics in the market.[80] Therefore, MOCRA "appear[s] to supersede" FDA regulations with reduced standards for cosmetic safety substantiations that manufacturers must provide prior to marketing.[81] Ultimately, by failing to offer uniform testing and evidence standards for manufacturer safety substantiations, FDA effectively enables manufacturers to downplay the risks associated with certain chemical ingredients before marketing their cosmetics.[82]

B. FDA Post-Market Enforcement Authority: Misbranding

In the cosmetic labeling space, FDA derives authority from both the FDCA and the Fair Packaging and Labeling Act.[83] Under both Acts, anything on or accompanying a cosmetic product's package constitutes labeling.[84] A cosmetic is misbranded if "its labeling is false or misleading in any particular," and FDA may issue warning letters or, with assistance from the Department of Justice, seek injunctions or criminal penalties against manufacturers for introducing misbranded cosmetics into interstate commerce.[85] Despite its authority to prohibit misbranded products in

80. *See* Consolidated Appropriations Act of 2023, Pub. L. 117-328, sec. 3502, § 608(c)(2); 40 Fed. Reg. 8,763, 8,916 (Mar. 3, 1975); JANET NUDELMAN, MODERNIZATION OF COSMETICS REGULATION ACT OF 2022 (MOCRA) SECTION-BY-SECTION ANALYSIS, BREAST CANCER PREVENTION PARTNERS 3 [hereinafter NUDELMAN, MOCRA ANALYSIS], https://www.bcpp.org/wp-content/uploads/2023/01/Cosmetic-Safety-Law-Reform_CSC-Section-by-Section-Analysis-1_10_23.pdf (last visited May 9, 2023) (asserting that the "customary or usual" standard is problematic "because it does not require manufacturers to consider real life—or foreseeable—uses or misuses of cosmetic products which is, ironically, the FDA's current regulatory condition of use standard for cosmetics").

81. Hill et al., *supra* note 72; *see* NUDELMAN, MOCRA ANALYSIS, *supra* note 80, at 3–4 (explaining that the safety standards under MOCRA are weaker than existing FDA cosmetic safety regulations).

82. *See* 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. 595, 623–24 (2014). The lack of safety substantiation standards results in "absolutely no incentive for a manufacturer to test its product ingredients for ill health effects" because such findings might lead FDA to determine a product is adulterated or misbranded, therefore, cosmetic manufacturers are "better served . . . to simply state that a product lacks appropriate safety data." *Id.*

83. *See* COSMETICS LABELING GUIDE, *supra* note 74, at 2 (explaining that while the Fair Packaging and Labeling Act ensures that cosmetic labels bear accurate information, the FDCA prohibits the marketing of misbranded cosmetics).

84. *See id.* at 5–6 (noting that a label is a written, printed, or graphic display of information affixed to or appearing on a cosmetic package or container).

85. *See* 21 U.S.C. § 362 (providing that a cosmetic is also misbranded if it does not bear the required labeling information or if the container is filled in a deceptive manner); SHEIKH & BODIE, *supra* note 71, at 7–8 (listing the various ways a cosmetic may be deemed misbranded); *see also About OCI*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/inspections-compliance-enforcement-

interstate commerce, FDA has not addressed common claims from nail care product manufacturers that feign product safety.[86] Although MOCRA requires products intended for professional use to bear ingredient listings, users might rely on marketing claims instead of unwieldy and confusing ingredient lists.[87]

Federal law provides that in determining whether a label is misleading, the agency will consider the extent to which the labeling "fails to reveal facts material . . . with respect to consequences which may result from the use of the article."[88] For example, FDA has utilized this provision in the cosmetic context before to find that a hair product containing methylene glycol, a liquid that becomes formaldehyde gas when heated, was misbranded because the manufacturer labeled it as "Formaldehyde Free."[89] Similar practices exist in the nail product industry.[90] In 2012, the California Department of Toxic Substances Control sampled twenty-five different nail polish brands for the presence of the toxic trio.[91] Out of the twelve products that claimed to be free of toluene, ten contained detectable concentrations of the chemical, and five of the seven products claiming to be free of DBP, formaldehyde, and toluene were falsely labeled.[92] While this practice could make for a misbranding offense, other industry labeling practices raise novel concerns.[93]

---

and-criminal-investigations/criminal-investigations/about-oci (Mar. 12, 2018) (describing the role of FDA's "criminal law enforcement arm").

86. *See* Crist, *supra* note 47 (discussing how claims such as "3-free" on products without the toxic trio are confusing because reformulations and substitutes are not necessarily safer).

87. *See* Consolidated Appropriations Act of 2023, Pub. L. 117-328, sec. 3502, § 609(c); Young, *supra* note 48 (noting that nail salon employees, consumers, and even public health researchers typically do not understand all the chemicals listed on ingredient labels and instead look to marketing labels).

88. *See* 21 U.S.C. § 321(n).

89. *See* U.S. FOOD & DRUG ADMIN., NO. 207094, WARNING LETTER TO MIKE BRADY (Aug. 22, 2011) [hereinafter FDA WARNING LETTER], https://wayback.archive-it.org/7993/20170111100925/http:/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm270809.htm.

90. *See* Amy Westervelt, *Not So Pretty: Report Finds Toxins in Nail Products Labeled Chemical-Free*, FORBES (Apr. 10, 2012), https://www.forbes.com/sites/amywestervelt/2012/04/10/not-so-pretty-report-finds-toxins-in-nail-products-labeled-chemical-free/?sh=11f095225386 (discussing a study finding that several nail polish manufacturers falsely claimed that their nail polishes did not contain toxic trio chemicals on the labeling).

91. *Id.*

92. *Id.*

93. *See id.* (noting that mislabeling ingredients may be illegal and states may exercise discretion in deciding whether to prosecute companies that mislabel ingredients).

In addition to "free-of" claims, manufacturers also use "number-free" (n-free)[94] labels that claim to exclude certain ingredients but consequentially shield the substitution of other harmful chemicals in their formulations.[95] These claims, which can range from 3-free (free of three harmful chemicals) to up to "13-free" (free of thirteen harmful chemicals), may claim to be free of materials not traditionally even used in nail polish.[96] Not only do different brands of nail products define label contents differently from one another, more recent n-free claims are often inconsistent with the list of ingredients excluded on previous labels of the same product.[97] The lack of regulatory scrutiny applied to these inconsistencies blurs the line between acceptable, safe ingredients and unacceptable ingredients, subjecting nail technicians to potential harm.[98]

While falsely claiming the absence of an ingredient on the cosmetic label violates misbranding regulations, it is unclear whether FDA may take a similar approach to nail product n-free claims and subsequent substitutions with other harmful chemicals.[99] For example, while methylene glycol in hair products *becomes* formaldehyde, the same cannot be said for toxins such as TPHP, which is *substituted* for DBP.[100] To address the ambiguity of labeling in light of the practice of "continual substitution of toxic chemicals for other toxic chemicals," FDA should provide clear n-free chemical list definitions that include common substitutions known to be harmful to health.[101]

---

94. *See Nail Polishes with 'N-Free' Labels Are Not Necessarily Free of Toxic Compounds*, AM. CHEM. SOC'Y (Oct. 10, 2018), https://www.eurekalert.org/news-releases/608494 (noting that growing concerns about the toxic trio motivated manufacturers to switch to other ingredients and label the products 3-free to mean free of the toxic trio; the trend grew and labels now tout products that are free of as many as thirteen chemicals despite the lack of standardization over which chemicals are included in certain number-free claims).

95. *See* Crist, *supra* note 47 (finding that most of the forty polishes sampled contained at least five of the twenty-two plasticizers that the study looked for, despite some making "n-free" toxin-free claims "ranging from '3-free' to '13-free'").

96. *See id.*; Frank C. Pagano, *X-Free Nail Polish: Scientific Evidence and Market Reality, A Commentary*, COSMS. & TOILETRIES, Nov.–Dec. 2021, at 54, 58, https://cosmeticsandtoiletries.textterity.com/cosmeticsandtoiletries/november_december_2021/MobilePagedReplica.action?pm=2&folio=54#pg63 (arguing that as manufacturers compete over how many ingredients they can claim a product to be free of, "many . . . claim to be free of materials that are not even used in nail polish").

97. *See* Crist, *supra* note 47.

98. *See id.* (noting chemical compositions are "especially important for nail salon workers because some of these toxins are linked to complications with fertility, thyroid issues, obesity and cancer").

99. *See* 21 U.S.C. § 362(a) (noting that a cosmetic is misbranded "if its labeling is false or misleading in any particular.").

100. *See id.*; FDA WARNING LETTER, *supra* note 89.

101. *See* Young, *supra* note 48 (arguing that FDA regulations "desperately" need an update because "the burden of safe nail polishes should not be on the consumer, nail salon, or employee.").

Without providing these definitions, FDA precludes consumer suits seeking to hold manufacturers accountable for misleading claims because courts are highly deferential to the agency's interpretations of labeling terms.[102] FDA is the agency best suited to prevent nail care product manufacturers from continuing to craft their own, inconsistent standards for safety claims.[103]

C. FDA Post-Market Enforcement Authority: Adulteration

Under the FDCA, a cosmetic is an article that is "intended to be . . . applied to the human body . . . for . . . beautifying . . . or altering the appearance."[104] Under the FDCA's adulteration provisions, a manufacturer may not use "any poisonous or deleterious substance" that makes a cosmetic "injurious" when it is used as intended, meaning when it is used according to directions on the label, or in the usual or customary way.[105] Introducing an adulterated product into interstate commerce may subject an individual or manufacturer to criminal penalties.[106]

The FDCA's "intended for use" scope in these definitions effectively precludes safety considerations for nail technicians.[107] For nail care products specifically, FDA assumes that otherwise harmful ingredients are safe when used on the nails because "the nail is a barrier, which prevents absorption."[108] For nail products, an intended use does not encompass contact from inhalation or dermal absorption.[109] However, nail technicians cannot escape exposures that fall outside of the intended-use

---

102. *See, e.g.*, Astiana v. Hain Celestial Grp., Inc., 783 F.3d 753 (9th Cir. 2015) (declining to review whether using terms such as "All Natural," "Pure Natural," and "Pure, Natural [and] Organic" on labels for cosmetics containing artificial ingredients constituted misbranding), *rev'g* 905 F. Supp. 2d 1013, 1014, 1016–17 (N.D. Cal. 2012); *cf.* POM Wonderful LLC v. Coca-Cola Co., 679 F.3d 1170, 1177 (9th Cir. 2012) ("If the FDA believes that more should be done to prevent deception . . . it can act . . . [b]ut . . . for a court to act when the FDA has not . . . would risk undercutting the FDA's expert judgments and authority.").

103. *See Astiana*, 783 F.3d at 760 (explaining that FDA reserves the power to define labeling terms); Crist, *supra* note 47 (highlighting the inconsistency of labeling terms and contents across various nail polishes and noting that ingredient exclusions are currently not validated by any third party).

104. 21 U.S.C. § 321(i).

105. *See* § 361(a).

106. *See* SHEIKH & BODIE, *supra* note 71, at 8.

107. *See* § 321(i); Fung, *supra* note 10, at 128 (arguing that FDA regulations fail to protect nail technicians from injury because salon workers use nail products for painting nails as intended).

108. *See Nail Care Products*, *supra* note 45.

109. *See id.*

scope.[110] Due to this statutory rigidity, FDA appears powerless to act on chemicals in nail care products when such chemicals are harmful through uses that the statute does not consider but that naturally follow from it.[111]

FDA has provided unclear interpretations for whether products containing chemicals exposed through unintended contact, such as under the conditions such products are used in the salon setting, are subject to adulteration actions.[112] In 2011, FDA warned a manufacturer of hair smoothing products that its merchandise was adulterated because it contained harmful levels of formaldehyde gas, for which the "primary route of exposure . . . is through inhalation," although the product's intended use was not for salon workers or clients to inhale.[113] Since FDA explored expanding on its interpretation of the statutory definition in the context of hair products "primarily for use by salon professionals in a salon setting," there may be opportunities for the agency to act under its current adulteration authority.[114] This ambiguous space requires clarification to unequivocally answer whether FDA can enforce adulteration provisions on harmful products with chemicals that nail technicians inhale or make dermal contact with during the application process and whether such contact is "customary or usual."[115]

Furthermore, a cosmetic is adulterated if "it consists in whole or in part of any filthy, putrid, or decomposed substance."[116] The statutory language of "putrid" and "filthy" connote acute, immediate risks rather than risks from the long-term exposures that nail technicians face.[117] However, recent developments under MOCRA provide that FDA can "consider, as

---

110. *See* POTENTIAL HEALTH AND SAFETY IMPACTS, *supra* note 41 (identifying dermal absorption and inhalation as "route[s] of human exposure" for toxic chemicals in nail care products).

111. *See* Sarah A. Walsh, *Beyond the Polish: An Examination of Hazardous Conditions in Nail Salons and Potential Solutions for the Industry in New York City*, 21 J.L. & POL'Y 243, 263 (2012) (noting that many nail products contain potentially harmful materials but remain on the market because they are "safe when used as directed").

112. *Compare Nail Care Products*, *supra* note 45 (noting that while an ingredient might be harmful when swallowed, FDA would not consider it harmful when used on the nail, which acts as a "barrier"), *with* FDA WARNING LETTER, *supra* note 89 (warning a manufacturer that its hair-smoothing product was adulterated because it contained chemicals that when inhaled are harmful).

113. *See* FDA WARNING LETTER, *supra* note 89.

114. *See id.*

115. *See* 21 U.S.C. § 361.

116. *See* § 361(b).

117. *See id.*; Watnick, *supra* note 82, at 602. The FDCA's focus on acute risks from cosmetics evinces a total lack of concern about the long-term effects of a cosmetic product, therefore "most cosmetic products are considered safe in the United States today, absent some meaningful proof of harm in the long-term, which is not regularly available." Watnick, *supra* note 82, at 602.

appropriate and available, the cumulative or other relevant exposure to the cosmetic product" in deeming that a cosmetic is adulterated because it has not been adequately substantiated for safety.[118] Because this provision is both unprecedented and optional for FDA, it is unclear whether the agency will use it to address nail product safety. Otherwise, absent a meaningful showing of harmful long-term effects—a showing that can be difficult to demonstrate—cosmetics such as nail products could remain on the market despite containing ingredients that are hazardous when they accumulate.[119]

FDA also affirmed that it can take action towards ingredients within its regulatory framework for cosmetics "based on reliable scientific information available" to it.[120] However, it is unclear whether FDA can accept existing research on nail product safety as adequate "reliable scientific information" for it to pursue an adulteration action.[121] Given that FDA has not provided the standards for the kind of information that surpasses the action standard, the extent of FDA's ingredient review authority in this area necessitates more clarity.[122]

Out of over 10,000 ingredients used in cosmetic formulations, FDA has only banned or restricted eleven ingredients that render cosmetics adulterated.[123] Compared to the nearly 2,000 substances that the European Union has banned from cosmetics, the brevity of FDA's restriction list demonstrates that the process of banning an ingredient in the United States

---

118. *See* Consolidated Appropriations Act of 2023, Pub. L. 117-328, sec. 3502, § 608(c)(2).

119. *See* Watnick, *supra* note 82, at 602 (arguing that most cosmetics are considered safe because meaningful proof of long-term harm is not readily available).

120. *See Prohibited & Restricted Ingredients in Cosmetics*, U.S. FOOD & DRUG ADMIN. [hereinafter *Prohibited & Restricted Ingredients*], https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics (Feb. 25, 2022) (noting that "the burden is on FDA to prove that a particular product or ingredient is harmful when used as intended . . . based on reliable scientific information available to [it].").

121. *See id.*; Harleen Arora & Antonella Tosti, *Safety and Efficacy of Nail Products*, COSMS., July 15, 2017, at 4–5, https://doi.org/10.3390/cosmetics4030024 ("No randomized control trials and few studies have been done to evaluate the safety and efficacy of nail varnish; most of the data available on this topic is in the form of case reports.").

122. *But see* Letter from Julie Menin, Comm'r, N.Y.C. Dep't Consumer Affs., to Dr. Stephen Ostroff, Acting Comm'r, U.S. Food & Drug Admin. (May 12, 2015), https://www1.nyc.gov/assets/dca/downloads/pdf/consumers/nyc-dca-letter-to-fda-may-12-2015.pdf (arguing that FDA currently *does* have the requisite data necessary to ban harmful chemicals in nail products and declare products containing them to be adulterated and noting that "[t]he FDA can rely on guidance from [the Occupational Safety and Health Administration (OSHA)] regarding the dangerous health effects of the toxic trio . . . and the extensive information the FDA already possesses . . . regarding the dangers posed by allowing these chemicals in cosmetic products").

123. *See Prohibited & Restricted Ingredients in Cosmetics*, *supra* note 120; Drabiak, *supra* note 69, at 88.

is not straightforward.[124] Even with evidence that an ingredient is harmful to human health, the road to banning a harmful ingredient is fraught with bureaucratic roadblocks and is vulnerable to leadership changes.[125] Prior FDA attempts to ban harmful cosmetic ingredients demonstrate that FDA may abandon the efforts due to shifting priorities or other unrelated issues despite "dozens of complaints," findings that an ingredient endangers salon workers, and scientists "mak[ing] the case for restricting" the use of an ingredient.[126] Among the unclear regulations, manufacturer indifference, and institutional infighting, the true victims are the salon workers who remain at risk of harmful product effects until FDA bans chemical culprits.

III. RULEMAKING AUTHORITY UNDER FDA'S RIGID COSMETIC FRAMEWORK

A. FDA Rulemaking Authority: Guidance and Definitions

Under the Administrative Procedure Act (APA), agencies may issue non-legislative, non-binding, procedural rules without undergoing the notice-and-comment process.[127] Non-legislative rules allow agencies to efficiently explain ambiguous legislation, advise the public on how the agency proposes to exercise its discretion, or manage intra-agency affairs without engaging in cumbersome procedures.[128] The Supreme Court clarified that "[a]n interpretive rule itself never forms the basis for an enforcement action[,]" and as such "does not impose any legally binding requirements on private parties."[129] Because informal guidance lacks the force of law, it would be

124. *See* 21 C.F.R. § 700.11–.27 (2022) (defining "adulterated" as any cosmetic product containing restricted cosmetic substance); Egeberg, *supra* note 67, at 322 (noting that chemicals banned in the European Union have been linked to cancer, birth defects, developmental and reproductive harm, and other devastating health issues).

125. *See* Roni Caryn Rabin, *The F.D.A. Wanted to Ban Some Hair Straighteners. It Never Happened*, N.Y. TIMES (Oct. 21, 2020), https://www.nytimes.com/2020/10/21/health/brazilian-blowout-formaldehyde-fda.html (describing how FDA's efforts to ban formaldehyde from hair straightening "halted" when a lawyer assigned to the task was "abruptly pulled off" the project just before President Trump took office).

126. *See id.* (providing that while salon workers assume that products on the market are safe, unsafe products may remain on the market due to FDA's failure to ban them).

127. *See* 5 U.S.C. § 553(b)(3)(A) (creating an exception for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice").

128. *See* TODD GARVEY, CONG. RSCH. SERV., R41546, A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW 7 (2017).

129. Kisor v. Wilkie, 139 S. Ct. 2400, 2420 (2019) (internal quotations omitted) (quoting Nat'l Mining Ass'n v. McCarthy, 758 F.3d 243, 251 (D.C. Cir. 2014)).

impossible for such guidance to exact sweeping, meaningful change.[130] Agencies also cannot use guidance to take significant action as that would undercut rulemaking requirements: even if an agency action falls into one of the three permissible categories of non-legislative rules, the action may still be subject to notice-and-comment rulemaking if it is "likely to have considerable impact on ultimate agency decisions" or if it will have a "substantive impact" on the rights of those under agency authority.[131]

B. FDA Rulemaking Authority: Informal Rulemaking

The notice-and-comment rulemaking process allows an agency to promulgate rules under its delegated legislative authority.[132] Final rules promulgated under APA § 553 are binding.[133] While FDA can achieve some change through rulemaking, it may be limited due to the rigid cosmetic statutory framework. Any rule that FDA promulgates must pass the review as defined by the Court in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*[134] *Chevron* provides that generally, if Congress has not spoken on the matter, courts defer to the agency's construction of the controlling statute as long as it is reasonable.[135] Therefore, while FDA can promulgate rules to restrict the use of certain ingredients, it cannot exceed the bounds of its statutory authority.[136]

IV. JUDICIAL CONSTRUCTION: LIMITS TO POTENTIAL FDA ACTION

FDA recognizes that it "does not have authority over the operation of salons or the practice of cosmetology," and that such workplace safety issues fall under the jurisdiction of OSHA.[137] Aside from the bounds of FDA's enforcement and rulemaking authority in the cosmetic space, there remains

130. *See id.*

131. *See* GARVEY, *supra* note 128, at 7 (internal quotations omitted) (quoting Pickus v. U.S. Bd. of Parole, 507 F.2d 1107, 1114 (D.C. Cir. 1974)).

132. *See id.* at 2.

133. *See id.*

134. 467 U.S. 837 (1984); *see* DANIEL T. SHEDD & TODD GARVEY, CONG. RSCH. SERV., R43203, *CHEVRON* DEFERENCE: COURT TREATMENT OF AGENCY INTERPRETATIONS OF AMBIGUOUS STATUTES 9 (2013).

135. *See* SHEDD & GARVEY, *supra* note 134, at 5.

136. *See id.* at 5–6 (noting that it is common for courts to consider legislative history and the meaning of statutory language to determine whether Congress has spoken clearly on an issue).

137. *See Hair Smoothing Products That Release Formaldehyde When Heated*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/cosmetic-products/hair-smoothing-products-release-formaldehyde-when-heated (Feb. 25, 2022).

a possibility that a court would deem FDA completely powerless to take action on safety issues specifically affecting the professional administration of a cosmetic, as opposed to the mere consumer use of one. While courts have not yet decided whether FDA possesses the authority to take on what is, at the root, an occupational hazard, current trends in jurisprudence suggest the Supreme Court might narrowly construe the enabling statutes of health and safety agencies.[138]

The Supreme Court recently found that OSHA overstepped its statutory purview when it mandated COVID-19 vaccines in the workplace, going too far by addressing a hazard affecting individuals both inside and outside the workplace.[139] As applied in the FDA context, a court narrowly construing the FDCA could similarly find that because OSHA has authority over workplace safety, FDA does not have the same authority to protect workers inside the workplace.[140] This possibility would pose a significant hurdle to FDA's authority to regulate nail products with special or specific consideration of technician safety.

---

138. *See* Nat'l Fed'n of Indep. Bus. (NFIB) v. OSHA, 142 S. Ct. 661, 666 (2022) (per curiam) (construing organic statute narrowly to strike OSHA health measure); Biden v. Missouri, 142 S. Ct. 647, 650 (2022) (per curiam) (quoting enabling statute to justify upholding Centers for Medicare and Medicaid Services' (CMS') vaccine mandate); *see also* Ala. Ass'n of Realtors v. U.S. Dep't of Health & Hum. Servs., 141 S. Ct. 2485, 2486 (2021) (per curiam) (holding plaintiffs were "virtually certain" to succeed on the merits because the Centers for Disease Control exceeded its authority by utilizing a statutory provision traditionally invoked for fumigation and pest extermination to promulgate a COVID-19 eviction moratorium).

139. *See NFIB*, 142 S. Ct. at 665 (holding the OSHA rule was an overly broad public health measure that went beyond the agency's purview over issues that affect safety in the workplace specifically). While the Court applied the major questions doctrine without determining the applicability of *Chevron* to justify a stay of the vaccine mandate rule, it is unlikely that a court would similarly conclude that an FDA assertion of its existing cosmetic rulemaking authority in the occupational context would run afoul of the doctrine. *See* West Virginia v. EPA, 142 S. Ct. 2587, 2610 (2022) (quoting Util. Air Regul. Grp. v. EPA, 573 U.S. 302, 324 (2014)) (finding a major questions issue where the EPA "'claim[ed] to discover . . . an unheralded power'" and "adopt[ed] a regulatory program that Congress had conspicuously and repeatedly declined to enact itself" (alteration in original)).

140. *Compare* 21 U.S.C. § 393(b)(1)–(4) ("[FDA] shall . . . protect the public health by ensuring that . . . cosmetics are safe and properly labeled; and . . . carry out [the section] . . . in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products"), *and Biden*, 142 S. Ct. at 650 (upholding a CMS vaccine mandate because a "core mission" of the agency is to ensure that healthcare providers protect the health of Medicare and Medicaid patients), *with NFIB*, 142 S. Ct. at 665 (striking OSHA's vaccine mandate because "[a]lthough COVID-19 is a risk that occurs in many workplaces, it is not an *occupational* hazard in most" and "[p]ermitting OSHA to regulate the hazards of daily life . . . would significantly expand OSHA's regulatory authority without clear congressional authorization").

In determining whether FDA has the authority to regulate nail care products in the occupational context, a court would likely review the issue under the *Chevron* doctrine.[141] Under the first step, a court would examine whether Congress directly spoke on the question at issue, and if so, the court would give effect to Congress's intent.[142] For example, if Congress already enacted legislation on product and occupational safety in nail salons without delegating authority to FDA, then Congress would have evidenced its view that FDA does not have jurisdiction.[143] This was the Supreme Court's reasoning in *FDA v. Brown & Williamson Tobacco Corp.*,[144] where it held that FDA lacked authority to regulate tobacco products because Congress had previously passed legislation concerning tobacco without providing FDA with authority to regulate in that area, suggesting it did not intend for FDA to have such power.[145] In response to the Court's ruling, Congress explicitly delegated authority to FDA to regulate tobacco products and curb their harmful public health outcomes through the Family Smoking Prevention and Tobacco Control Act.[146]

Whether FDA action on nail care products can survive the Supreme Court's trend toward narrow construction relies on congressional support for FDA's regulation in this area.[147] Under step two of *Chevron*, if a court finds Congress has not directly spoken on the issue, it examines whether the agency's construction is reasonable; if so, the Court will accept the agency's

141. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 125–26 (2000) (applying *Chevron* to determine whether FDA had authority to regulate tobacco products); City of Arlington v. FCC, 569 U.S. 290, 293 (2013) (affirming that *Chevron* applies to statutory provisions that define the scope of an agency's authority). *But see* KATE R. BOWERS, CONG. RSCH. SERV., IF12077, THE MAJOR QUESTIONS DOCTRINE (2022) (suggesting that the Court's recent move towards applying the major questions doctrine as an independent principle means that *Chevron* might not apply at all if a court determines the agency's claim of regulatory authority runs afoul of the doctrine).

142. *See* SHEDD & GARVEY, *supra* note 134, at 5–6.

143. *See, e.g.*, *Brown & Williamson*, 529 U.S. at 126 ("Congress has clearly precluded the FDA from asserting jurisdiction . . . .").

144. 529 U.S. 120 (2000).

145. *See id.* at 126, 142–43 (arguing that there is no room for tobacco as "drugs" or "devices" in FDA's regulatory scheme because tobacco could not be used safely for any therapeutic purpose).

146. *See* Jeremy R. Singer, *Taking on Tobacco: The Family Smoking Prevention and Tobacco Control Act*, 34 NOVA L. REV. 540, 546–47 (2015) (noting that the Family Smoking and Tobacco Control Act provided statutory language that enabled FDA to regulate tobacco, thereby preserving FDA's jurisdiction over tobacco in face of future industry challenges under *Brown & Williamson*).

147. *See* NFIB v. OSHA, 142 S. Ct. 661, 665 (2022) (per curiam) ("Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided.").

interpretation.[148] Although courts usually defer to the agency during this step, the Supreme Court's recent constructions of health and safety actions present the risk that a court may disapprove of FDA's action on professional exposure levels in the workplace as an impermissible overstep of the agency's statutory bounds.[149] To cement FDA's rulemaking and enforcement powers over the effects of nail care products in the salon setting, Congress should directly and unequivocally express support for FDA authority in this context.

V. COSMETIC REFORM PROPOSALS

A. Recently Passed Legislation Falls Short

Advocates and lawmakers have attempted to update cosmetic safety standards for years, and in 2022, a reform effort successfully altered the nation's cosmetics regime for the first time since 1938.[150] Passed as part of a consolidated appropriations bill, MOCRA "emerged in the wake of heightened FDA and consumer attention toward the safety of cosmetic products" and boasts significant strides in FDA's authority over cosmetics.[151] These strides include providing FDA with mandatory recall authority, mandated facility registration and product listings, directives for FDA to promulgate guidelines dictating safe cosmetic manufacturing practices, and enforcement provisions that classify the failure to adhere to any of MOCRA's requirements as adulteration or misbranding.[152]

However, the Act did not go as far as imposing any pre-market review for cosmetics.[153] And unlike in a prior reform effort, cosmetic ingredient review provisions are "notably absent"—Congress declined to grant FDA the authority to analyze specific cosmetic ingredients for safety under MOCRA.[154] In choosing MOCRA as its vehicle for cosmetic reform,

148. *See* SHEDD & GARVEY, *supra* note 134, at 6.

149. *See NFIB*, 142 S. Ct. at 665–66 (examining language in the "Organic Statute"); Biden v. Missouri, 142 S. Ct. 647, 650 (2022) (quoting enabling statute).

150. *See* REEVES ET AL., *supra* note 31, at 1.

151. *See id.*

152. *See id.* at 1–2.

153. *See id.* at 1.

154. *See* EVA TEMKIN, LISA DWYER, JESSICA RIGEL, ALLISON KASSIR, JESSICA GREENBAUM & JONATHAN TRINH, KING & SPALDING, ACT II: THE SENATE UNVEILS ITS DRAFT 2 (2022) [hereinafter SENATE UNVEILS ITS DRAFT], https://www.kslaw.com/attachments/000/009/704/original/Act_II_-_The_Senate_Unveils_Its_Draft.pdf (noting that MOCRA requirements "are not as sweeping as anticipated" given "buzz" over the previously-introduced Personal Care Products Safety Act, which included provisions requiring FDA to review the safety of cosmetic ingredients annually).

Congress fell short on implementing the ingredient review threshold necessary to protect nail technicians from harmful nail care product exposures. As a broad and ultra-encompassing category, cosmetics and accompanying regulations affect various intersectional groups and occupations in different ways.[155] Nail technicians represent a distinctly vulnerable population due to factors such as minority status, workplace agency, and health literacy.[156] To properly address these issues at the root, legislation must grant FDA the ability to conduct precautionary ingredient risk evaluations with special consideration of vulnerable populations such as nail technicians.

B. Ingredient Review Success Story: A Look into the EPA's TSCA Reform

In 2016, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Chemical Safety Act), which amended the Toxic Substance Control Act (TSCA).[157] The Lautenberg Chemical Safety Act requires the EPA to conduct safety reviews for chemical substances currently in the market, as well as new chemicals before they enter the market.[158] Prior to the Lautenberg Chemical Safety Act's amendments, the EPA's authority over ingredient review under TSCA was as similarly limited as FDA's current cosmetic regime.[159] For example, the pre-amended TSCA required manufacturers to receive the EPA's approval before chemicals could

155. *See* Marie Boyd, *Gender, Race & the Inadequate Regulation of Cosmetics*, 30 YALE J.L. & FEMINISM 275, 286 (2018) (providing that the current cosmetic law limitations can impact people differently, as the "risks to an African American woman who uses chemical relaxers and deep conditioners; a Vietnamese immigrant woman who works in a nail salon; and a white woman who uses dark hair dyes may differ").

156. *See generally* SHARMA ET AL., *supra* note 14 (discussing the demographic makeup and unique vulnerabilities of nail salon workers); West, *supra* note 22 (same).

157. *See* Cory Gerlach, *New Toxic Substances Control Act: An End to the Wild West for Chemical Safety?*, HARV. SCI. IN THE NEWS: BLOG (Oct. 25, 2016), https://sitn.hms.harvard.edu/flash/2016/new-toxic-substances-control-act-end-wild-west-chemical-safety/.

158. *See id.*; *see also* Kraus, *supra* note 30, at 174 (noting that Toxic Substances Control Act (TSCA) provisions "apply only to chemical substances, not the end products" like cosmetics in which the chemicals are used).

159. *See* Kraus, *supra* note 30, at 177. In the pre-Lautenberg TCSA, "[n]either the TSCA nor the FDCA requires personal care product manufacturers to perform toxicology tests on their products or provide the public with safety data." *Id.*; *see also* Press Release, U.S. Environmental Protection Agency, EPA Proposes to Ban Ongoing Uses of Asbestos, Taking Historic Step to Protect People from Cancer Risk (Apr. 5, 2022), https://www.epa.gov/newsreleases/epa-proposes-ban-ongoing-uses-asbestos-taking-historic-step-protect-people-cancer-risk (describing the effect of a 1991 court decision that "largely overturned EPA's 1989 ban on asbestos" and announcing a proposed rule to prohibit ongoing use of asbestos under the newly-enacted Lautenberg Act).

hit the market.[160] However, the EPA could only review data generated by the manufacturers themselves.[161] Similarly, FDA requires manufacturers to substantiate product safety before marketing but allows beauty manufacturers to test for safety in any way they choose.[162] The pre-amended TSCA also presented a catch-22 wherein the EPA had to show a chemical's potential harm before it could compel testing to determine whether the chemical posed an "unreasonable risk" to public health or the environment, despite not having ready access to safety data that manufacturers were not required to provide.[163] Similarly, while the "burden is on FDA to prove that a particular product or ingredient is harmful when used as intended," FDA cannot require manufacturers to share ingredient safety data with the agency.[164] The key changes that the Lautenberg Chemical Safety Act implemented included toxicity review, risk-ranking and management, and consideration for vulnerable populations.[165] The EPA may now require more toxicity testing before approving chemicals, must develop a screening process for all existing chemicals that ranks them according to their level of risk, and must consider feasible alternatives and vulnerable populations in its review.[166]

Under the TSCA, the EPA lacks the authority to regulate chemicals distributed in commerce solely for use in cosmetics; however, it can regulate those same chemicals when they are meant to be used in other products.[167] This is because the TSCA's definition for "chemical substance" excludes substances that meet the definition of "cosmetic" under the FDCA.[168] As demonstrated by the EPA's power to review chemical components found in nail care products for non-cosmetic purposes, FDA requires a similar level of

160. *See* Gerlach, *supra* note 157.

161. *See id.*

162. *See* 21 C.F.R. § 740.10 (2022); *The FDA Needs More Power to Regulate Toxic Chemicals in Cosmetics*, SCI. AM. (Nov. 1, 2017), https://www.scientificamerican.com/article/the-fda-needs-more-power-to-regulate-toxic-chemicals-in-cosmetics/ (noting that FDA "requires no specific tests before a company brings a new product with a new chemical to market").

163. *See* Kraus, *supra* note 30, at 180 (noting that because manufacturers were not required to generate safety data and risk information under the TSCA, the EPA usually did not have enough information to compel new safety and risk testing).

164. *Prohibited & Restricted Ingredients*, *supra* note 121.

165. *See* Gerlach, *supra* note 157.

166. *See id.*

167. The EPA declined a TSCA rulemaking petition requesting that the agency take action against hazardous chemical mixtures in cosmetics because although the EPA can regulate chemical mixtures, it lacked jurisdiction over chemical mixtures that are "manufactured, processed, or distributed in commerce for use as a cosmetic." Denial of Requested Rulemaking, 86 Fed. Reg. 64,129, 64,132 (Nov. 17, 2021).

168. 15 U.S.C. § 2602(2)(B)(vi).

reform that emphasizes ingredient review.[169] While not all-encompassing, the key aspects of the Lautenberg Chemical Safety Act address the elements necessary to analyze ingredient safety with considerations for the levels of exposure experienced by vulnerable populations.[170] A similar regime at FDA would provide the agency with the authority to restrict harmful chemical exposures in manicure products.

VI. RECOMMENDATIONS

A. Granting Ingredient Review and Management Authority

Granting cosmetic ingredient review authority to FDA and increasing the agency's resources is the most significant and important step toward reducing or eliminating harmful chemical exposures from nail care products. Mandated ingredient review would give FDA greater bandwidth to ensure it actually and effectively analyzes ingredients on the market for safety.[171] Considering the EPA's improved ingredient authority, Congress should utilize the key aspects of the Lautenberg Chemical Safety Act reform as a guide.[172]

Congress must take on Lautenberg Chemical Safety Act-level reform to effectively push out harmful chemicals in manicure products that jeopardize occupational health. To do so, Congress should reconsider and pass the Safe Cosmetics and Personal Care Products Act (SCPCPA), last introduced in 2019.[173] The SCPCPA, as last introduced, aimed to amend the FDCA and expand FDA's regulatory powers over cosmetics.[174]

---

169. *See* Kraus, *supra* note 30, at 174–76. The EPA's authority under TSCA entails "assessing the risk of chemicals before they are put into consumer products," so although cosmetics ultimately fall within the purview of FDA, they may contain TSCA-regulated chemicals; for example, while dibutyl phthalate is an ingredient in nail polish, it falls under the purview of TSCA because it is also used as a chemical solvent in other industries. *Id.*

170. *See supra* Part V.B.

171. *See* Fung, *supra* note 10, at 140–41 (arguing that "[w]ithout FDA authority of pre-market approval . . . the cosmetic industry is wholly self-regulated, resulting in scarce protections to consumers and profession[al]s who use nail products on a daily basis").

172. *See supra* Part V.B.

173. Safe Cosmetics and Personal Care Products Act of 2019 (SCPCPA), H.R. 4296, 116th Cong. (2019); *see* Lauren Nardella & Ryan Nelson, *Schakowsky's Loaded Cosmetics Bill Described As 'Floor, Not A Ceiling' For States to Build On*, HBW INSIGHT (Oct. 1, 2019), https://hbw.pharmaintelligence.informa.com/RS149264/Schakowskys-Loaded-Cosmetics-Bill-Described-As-Floor-Not-A-Ceiling-For-States-To-Build-On (discussing reintroduction of the SCPCA). The SCPCPA has been introduced in Congress three times since 2013. Tecson, *supra* note 75, at 136.

174. *See* Nardella & Nelson, *supra* note 173.

The major provisions of the SCPCPA mirrored those of the Lautenberg Chemical Safety Act; they include toxicity review, risk-ranking and management, and consideration for vulnerable populations.[175]

In terms of toxicity review, the SCPCPA sought to provide resources to FDA and mandate it immediately add twenty ingredients to a priority assessment list (PAL) for review, after which it would be required to assess ten ingredients annually until it reviewed all cosmetics chemicals under the "reasonable certainty of no harm" safety standard defined in the Act.[176] Given that MOCRA does not currently mandate annual ingredient reviews, this provision would constitute a meaningful shift towards safer ingredients on the market.[177] When considering which chemicals to place on the PAL, FDA would not only need to consider scientific evidence linking the chemical to harmful health effects, but also prioritize chemicals that disproportionately impact a certain racial, ethnic, or occupational community.[178] Including this language would bring nail product chemical safety into the forefront, as these chemicals unfairly harm the nail technician profession—a profession comprised mainly of women who immigrated to the United States.[179] This mandate would also significantly expand ingredient reviews, currently left up to manufacturers to conduct.[180]

If reintroduced, the SCPCPA would also establish a heightened safety standard that requires cosmetics to present "a reasonable certainty of no harm . . . and protects the public from any known or anticipated adverse health effects associated with the cosmetic or ingredient."[181] The SCPCPA

175. *See id.*

176. *See* H.R. 4296 § 616(a)(2) (providing that FDA shall add twenty ingredients to the initial Priority Assessment List (PAL)); § 616(d)(2) (providing that FDA shall annually add at least ten additional ingredients to the PAL until all ingredients used in the formulation of cosmetics have been evaluated for safety); § 614(a)(1) (setting safety review standard as a "reasonable certainty of no harm").

177. *See* SENATE UNVEILS ITS DRAFT, *supra* note 154, at 2 (noting that MOCRA does not require FDA to review the safety of cosmetic ingredients annually).

178. *See* H.R. 4296 § 616(a)(3) (noting that in determining placement on the PAL, the FDA must "consider the scientific evidence linking that ingredient to harm and conduct further prioritization based on whether the ingredient . . . is of particular concern to a community disproportionately impacted by cosmetic chemicals in products marketed to them because of their particular race, ethnicity, or occupation").

179. *See* SHARMA ET AL., *supra* note 14, at 5 (noting that non-citizen women in particular dominate the nail salon industry in the United States, with 81% and 79% of salon workers being women and foreign-born respectively).

180. *See* Kraus, *supra* note 30, at 177 (detailing how the industry-run Cosmetic Ingredient Review panel conducts its own ingredient evaluations).

181. *See* H.R. 4296 § 614(a)(1).

further defines a "reasonable certainty of no harm" as one in which "the likely level of exposure . . . presents not more than a one in a million risk for any adverse health effect in any vulnerable population."[182] FDA currently uses a "reasonable certainty of no harm" safety standard for cosmetic color additives, which require pre-market approval.[183]

Applying the "reasonable certainty of no harm" safety standard to cosmetics would require manufacturers to either completely remove many of the existing chemicals that may adversely affect health or explore safer alternatives.[184] The burden would fall on manufacturers, rather than FDA, to prove ingredient safety, increasing manufacturer accountability as well as the likelihood of obtaining better data concerning the long-term effects of nail product chemicals. Finally, using this safety standard, FDA can address nail product exposures that have higher impacts on nail technicians than on the average consumer.[185]

The SCPCPA would also fast-track the ban of chemicals known to be harmful to nail technicians, which would be more expedient than an FDA-initiated ban for each individual chemical.[186] Among a list of a dozen of the most toxic chemicals found in cosmetics, the SCPCPA would immediately ban the toxic trio.[187] Additionally, some states have already enacted bans of chemicals such as DBP and formaldehyde in cosmetics sold in-state.[188] As these state-specific bans are expected to significantly impact manufacturers who wish to sell in these states, Congress should take advantage of the opportunity to preserve these bans through federal law.[189] Without doing so,

---

182. *See* § 614(a)(2)(A).

183. *See* Public Comment, Janet Nudelman, Sr. Dir. of Program & Pol'y, Breast Cancer Prevention Partners, Response to the *Modernization of Cosmetics Regulation Act*, Title VII of the Food and Drug Administration Safety and Landmark Advancements Act of 2022 Discussion Draft (May 22, 2022) at 3 [hereinafter, Nudelman, Response], https://www.bcpp.org/wp-content/uploads/2022/06/Public-Comment-for-Senate-HELP-Cos-Safety-Discussion-Draft-22-May-2022.pdf (noting that a safety definition of a "reasonable certainty of no harm" has "been the standard for the safety of food additives and the colors in cosmetics for more than 50 years").

184. *See* Jacobs, *supra* note 39, at 107.

185. *See* H.R. 4296 § 611(9) (including a specifically defined safety standard that accounts for the level of exposure in "any vulnerable population," as well as consideration for the impact of "cumulative exposure from all sources").

186. H.R. 4296 § 616(b)(2)(A); *cf.* Rabin, *supra* note 125 (describing how FDA-initiated efforts to ban formaldehyde in hair products ultimately failed due to shifting priorities and leadership changes).

187. *See* H.R. 4296 § 616(b)(2)(A).

188. *See, e.g.*, MD. CODE ANN., HEALTH–GEN. § 21-259.2 (West 2022) (effective Jan. 1, 2025) (Maryland ban); CAL. HEALTH & SAFETY CODE § 108980 (West 2023) (effective Jan. 1, 2025) (California ban).

189. *See, e.g.*, Press Release, Breast Cancer Prevention Partners, California First State to Ban

federal preemption could threaten more stringent state requirements designed to protect professionals, such as nail technicians, and consequentially result in weaker nationwide cosmetic reform. The SCPCPA as currently written protects against this possibility because it does not contain a preemption clause.[190]

In terms of risk-ranking, the SCPCPA would provide FDA with the authority to categorize cosmetic ingredients into "prohibited," "restricted," "safe without limits," and "priority assessment."[191] Risk-ranking would aid the agency in prioritizing its resources toward the most harmful and pervasive chemicals, such as those in nail products.

Finally, the SCPCPA would address severe chemical hazard exposures affecting salon workers and communities of color and would do so by defining the cosmetic safety standard to take into account the level of exposure "in any vulnerable population," as well as consider the "impact of cumulative exposure from all sources."[192] While MOCRA provides that FDA "may consider" cumulative exposures to cosmetic products when determining whether a cosmetic is safe, this consideration is permissive, so manufacturers are not required to consider the impact of cumulative exposures when substantiating their cosmetics for safety.[193] On the other hand, the SCPCPA would require the consideration of cumulative exposures—under the SCPCPA's standard, whether a nail product can be rendered safe would depend on its long-term impact on nail technicians under the conditions that the nail technicians typically work in, which includes working for long hours.[194] The SCPCPA would also fund research into safer alternatives to the hazardous ingredients such as those found in nail care products.[195]

The SCPCPA died in committee at the end of the 116th Congress.[196] Several commentators have discussed the SCPCPA's superiority over other cosmetic-reform bills in protecting against harmful occupational

---

24 Toxic Chemicals in Personal Care Products and Cosmetics, (Sept. 30, 2020), https://www.bcpp.org/resource/california-first-state-to-ban-24-toxic-chemicals-in-personal-care-products-and-cosmetics/ (noting that "if a manufacturer is required to satisfy California standards, it will likely adhere to the same high standard with the products it sends to the rest of the country").

190. *See* Nardella & Nelson, *supra* note 173.

191. *See id.*

192. *See id.*; H.R. 4296, 116th Cong. § 611(9) (2019).

193. *See* Consolidated Appropriations Act of 2023, Pub. L. 117-328, sec. 3502, § 608(c)(2); MOCRA ANALYSIS, *supra* note 80, at 3.

194. *See* Nardella & Nelson, *supra* note 173; H.R. 4296 § 611(9); *Health Hazards in Nail Salons*, *supra* note 8.

195. *See* Nardella & Nelson, *supra* note 173.

196. *See* H.R. 4296.

exposures, and some have argued that the SCPCPA should be re-introduced, noting the benefits the bill would provide to vulnerable populations, such as nail salon technicians.[197]

B. Firmly Establishing FDA's Jurisdiction over Nail Salon Products

Under the FDCA, whether "customary or usual" conditions of use may include occupational uses and exposures for the purpose of adulteration actions presents another area of statutory ambiguity.[198] Current judicial interpretations of health and safety statutes further compound this uncertainty.[199] FDA could take advantage of this ambiguity and argue that, because of the ubiquity of nail salons, applying nail polish has become a "customary" use of the product.[200] The agency could then promulgate a rule that identifies occupational-specific consequences of nail product use as a condition of use that is subject to adulteration enforcement. However, it is unclear whether a court would read such a rule as contravening congressional intent.[201] Although FDA has considered salon-setting uses within its product safety purview before, current judicial trends suggest that congressional action would be the most effective vehicle to cement FDA's authority in this space.[202]

As currently drafted, the SCPCPA contains a provision defining "professional use," which, if passed, would clarify FDA's authority to regulate "the application of a cosmetic to a human customer or client by an employee or contractor of a hair salon, nail salon, beauty salon, spa, or other [similar]

197. *See* Jacobs, *supra* note 39, at 106–10, 120 (arguing that the SCPCPA should be passed instead of the Personal Care Products Act or FDA Cosmetic Safety and Modernization Act); Tecson, *supra* note 75, at 129 (arguing that Congress should reintroduce the SCPCPA); Watnick, *supra* note 82, at 643 (recognizing the prior introduction of the SCPCPA as "the strongest" of recent federal proposals). Congresswoman Jan Schakowsky sponsors a current bill package that would ban a list of toxic chemicals from cosmetic products, but these bills leave out provisions of the SCPCPA that should be preserved due to the ingredient-review focus. *See* Press Release, Women's Voices for the Earth, New Federal Bill Package Will Make Safer Beauty Available to All (July 29, 2021), https://womensvoices.org/2021/07/29/new-federal-bill-package-will-make-safer-beauty-available-to-all (describing a bill package that would ban certain ingredients, require transparency in cosmetics labeling, and fund research into cosmetic effects on vulnerable populations).

198. *See* 21 U.S.C. § 361(a); *supra* Part II.C.

199. *See supra* Part IV.

200. *See* Ilic-Godfrey, *supra* note 3 (discussing the popularity of nail services and projecting the growth of the nail salon industry); § 361.

201. *See supra* Part IV; § 361.

202. *See supra* Part IV.

establishment . . . ."[203] However, the term only refers to FDA's authority under the bill's section concerning ingredient labels.[204] Similarly, MOCRA defines professional use only in the labeling context.[205] Therefore, if Congress reconsiders the SCPCPA, lawmakers should expand the Bill to include a provision that expresses Congress' intent for FDA to regulate products as they relate to both consumers and those who apply the products, such as nail technicians. Alternatively, Congress could pass a standalone bill clarifying this authority to secure subsequent rulemaking power for FDA.

C. Clarifying Ambiguous Regulations to Improve Nail Product Safety

While congressional action would have the most potential to enact meaningful and sweeping reform, FDA can utilize its APA rulemaking authority and promulgate beneficial clarifications for existing, ambiguous regulatory language. These areas include defining the threshold for manufacturers' self-determined safety substantiations, defining the level of information necessary to ban ingredients, and defining certain marketing claims. APA informal rulemaking is the most effective vehicle to address these issues because agencies cannot use guidance documents to take significant or binding action.[206] By limiting the proposed rules to merely clarify how it plans to act under existing statutory language, FDA would lower the risk that it will run afoul of the APA.[207]

FDA should define a threshold for information that supports an "adequate substantiation of safety"; while both FDA regulations and MOCRA mandate safety substantiations for cosmetics, neither specify any testing or evidence requirements for manufacturers to meet.[208] One existing area of law that can serve as a model for cosmetic safety substantiation is the standard in FDA's regulations of manufacturer self-determination of safety within the food additive approval regime.[209] FDA currently requires that for an ingredient

---

203. *See* H.R. 4296, 116th Cong. § 611(8)(a) (2019).

204. *See id.* § 613.

205. *See* Consolidated Appropriations Act of 2023, Pub. L. 117-328, sec. 3502, § 609(c).

206. *See* GARVEY, *supra* note 128, at 7.

207. *See id.*

208. *See* 21 C.F.R. § 740.10(a) (2022) (stating that ingredients in cosmetic products "shall be adequately substantiated for safety prior to marketing"); Consolidated Appropriations Act of 2023, Pub. L. 117-328, sec. 3502, § 608(a) (stating that "a responsible person for a cosmetic product shall ensure . . . that there is adequate substantiation of safety of such cosmetic product"); SHEIKH & BODIE, *supra* note 71, at 11–12.

209. *See* Paulette Gaynor, *How U.S. FDA's GRAS Notification Program Works*, FOOD SAFETY, Dec. 2005–Jan. 2006, https://www.food-safety.com/articles/4126-how-us-fdas-gras-notification-program-works (stating that a food manufacturer can self-determine that an additive substance is

to be "generally recognized as safe" (GRAS) for use in food, the safety of food additive formulations must be supported by published, peer-reviewed scientific data.[210] FDA should adopt this threshold for cosmetics to compel manufacturers to invest in methodic and thorough testing, or to find up-to-date and reliable data to adequately support ingredient safety before distributing their cosmetic products in the market.

One drawback of defining this standard through rulemaking is that FDA lacks the statutory authority to mandate regulated parties to submit safety data to the agency for review.[211] However, FDA can employ a system similar to its food additive GRAS affirmation process through which manufacturers voluntarily send safety substantiations for FDA examination.[212] From there, the agency can take no action or notify the manufacturer that the supporting data is insufficient.[213] While the process is voluntary, it incentivizes manufacturers to go through FDA review rather than make their own GRAS declarations as they may risk retail loss if they fail to provide safety information.[214] If this becomes the norm, nail products with formulations reviewed for safety by FDA may be more successful and prevalent in the market. Incentivizing manufacturers to share their cosmetic safety data with FDA would be especially beneficial in curbing the long-term effects of nail product chemical exposures, given FDA's new authority to consider cumulative exposures in determining whether a cosmetic product has been adequately substantiated for safety.[215]

Through rulemaking, FDA could also clarify the level of "reliable scientific information" required for the agency to ban or restrict a cosmetic ingredient.[216] FDA can interpret this term to encompass published studies

---

"generally recognized as safe" (GRAS) and place it on the market without FDA's approval).

210. 21 C.F.R. § 170.30 (2021) ("General recognition of safety . . . shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.").

211. *See* Boyd, *supra* note 155, at 324 (noting that FDA has recognized that it "has no statutory authority to require mandatory cosmetic product reporting").

212. *See* Gaynor, *supra* note 209 (describing how FDA issued a proposed rulemaking to establish a GRAS notification program that provides a voluntary mechanism for manufacturers to inform FDA that their substance is GRAS).

213. *See id.*

214. *See* PETER BARTON HUTT, RICHARD A. MERRILL, LEWIS A. GROSSMAN, NATHAN CORTEZ, ERIKA FISHER LIETZAN & PATRICIA J. ZETTLER, FOOD & DRUG LAW 760 (5th ed. 2022) (noting that very few processors will purchase ingredients for which the supplier cannot provide documentation of FDA approval or GRAS acknowledgement).

215. *See* Consolidated Appropriations Act of 2023, Pub. L. No. 117-328, sec. 3502, § 608(c)(2).

216. *See Prohibited & Restricted Ingredients*, *supra* note 200.

that suggest harm from exposures through elevated uses in common occupational settings, rather than evidence of acute reactions alone. As published studies denoting the harmful effects of nail salon product exposures already exist in the nail technician context, such an interpretation could better enable FDA to ban pervasive, toxic ingredients used in nail products.[217]

Finally, FDA can use rulemaking to standardize the various n-free labeling claims to include specific chemical lists with common harmful substitutions such as TPHP, rather than chemicals not typically used in nail products.[218] Standardizing such claims would improve technician awareness of the specific harm associated with certain chemicals in nail products.[219] This practice would also keep manufacturers accountable by requiring them to truthfully provide safer alternatives.[220] Standardized terms would notably benefit health-conscious nail salons seeking to protect both technician and consumer health.[221]

CONCLUSION

Every day at work, nail technicians experience exposures to reproductive toxins, asthmagens, irritants, and potential carcinogens in the products essential to their job performance.[222] While occupational risks in the nail salon industry may not constitute immediate physical dangers, chemical exposures at the levels nail technicians experience pose threats to long-term occupational health.[223] However, FDA lacks adequate authority to regulate nail product safety in this context.[224]

---

217. *See generally, e.g.*, Ma et al., *supra* note 7, at 1,168 (discussing findings from a community-based participatory research study that explored various "health problems that emerged or worsened after participants started working in the nail salon industry"); Forster, *supra* note 12 (discussing a University of Colorado study that identified high levels of cancer-causing chemicals from products in nail salons and statistically modeled the long-term effects of such chemicals on nail technicians to find an increased risk of cancer).

218. *See* Jacobs, *supra* note 39, at 124 (noting current legislation does not define cosmetic labeling terms).

219. *See* Patel, *supra* note 67, at 48 (arguing that standardized cosmetic labeling claims would "provide for increased consumer awareness of the specific harm caused by the specific chemicals used in various products").

220. *See id.* (noting that standardizing labeling claims would "reveal whether products are truly 'clean,' 'natural,' et cetera").

221. *See* Jenny Gold, *California Nail Salons Start to Invest in Worker Safety*, NPR (Jan. 12, 2017), https://www.npr.org/sections/health-shots/2017/01/12/509315426/california-nail-salons-start-to-invest-in-worker-safety (discussing the California Healthy Nail Salon Collaborative in which participating salons utilize less toxic nail products in efforts to protect worker safety).

222. *See* Ma et al., *supra* note 7, at 1,169.

223. *See id.*

224. *See The FDA Needs More Power to Regulate Toxic Chemicals in Cosmetics*, *supra* note

Current statutory definitions, by design, exclude consideration of harmful chemical exposures that nail technicians experience.[225]

FDA's rulemaking can help to clarify existing protections as applied to nail technicians and will be easier than pursuing Congressional action.[226] However, while FDA may pursue administrative rulemaking to set industry standards for pre-market safety substantiations and health-oriented labeling claims, the agency may face judicial-review barriers if it attempts to mandate industry action.[227] Therefore, true effective reform relies on congressional action. To effectively rein in manicure manufacturers and protect nail technicians, Congress should re-introduce and adopt the SCPCPA, which would encompass major strides toward ingredient reform and would effectively ban or restrict dangerous chemicals found in manicure products.

162 (noting that FDA lacks the authority to require pre-market safety approval and manufacturers are not required to share safety information).

225. *See* Fung, *supra* note 10, at 128 (arguing that FDA's current limits on what is considered permissible exposure to harmful chemicals fail to protect nail technicians from injury and "need to be updated and lowered to reflect current scientific knowledge" of harms).

226. *See* Nardella & Nelson, *supra* note 173 (noting that Congress is not prioritizing cosmetic reform).

227. *See supra* Part III.B.