BAD INK: TOUCHING UP THE FDA'S REGULATION OF TATTOO INK

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* I dedicate this Note to my mom, Robin D. Kearney.

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I. INTRODUCTION

Once confined to the peripheries of American society and stigmatized as the mark of sailors and jailbirds,[1] today, tattoos are embedded in the stratum of popular culture.[2] Formerly practitioners of a niche art form, tattoo artists have found fame on reality television shows, reflecting the art form's integration into the mainstream.[3] Tattoos are on display by A-List actors, runway models,[4] Grammy-winning musicians,[5] Olympic athletes,[6] and even politicians on the floor of Congress.[7] Given the prevalence of famous tattoos, the number of "inked" Americans is unsurprisingly high. While on the rise since the 1970s, the last fifteen to twenty years saw a more sudden uptick in the number of Americans

1. *See* Jocelyn Camacho, The Tattoo: A Mark of Subversion, Deviance, or Mainstream Self Expression? 1–9 (Aug. 7, 2011) (Ph.D. dissertation, University of South Florida) (on file with Digital Commons @ University of South Florida); Farah Mohammed, *How Tattoos Became Middle Class*, JSTOR DAILY (June 14, 2018), https://daily.jstor.org/how-tattoos-became-middle-class/.

2. *See* Camacho, *supra* note 1, at 10.

3. *See, e.g.*, Jasmine Dando, *Tattoo Shows*, IMDB, https://www.imdb.com/list/ls091575085/ (last visited May 1, 2025) (listing nine television shows about tattoos).

4. *See* Anjelica Oswald, *Here Are 30 of the Most Iconic Celebrity Tattoos Updated*, BUS. INSIDER (Apr. 24, 2019, 11:05 AM), https://www.insider.com/celebrity-iconic-tattoos-inspiration-2017-9.

5. For example, Lady Gaga, a fourteen-time Grammy winner, has at least twenty-four tattoos. *Lady Gaga*, GRAMMY AWARDS, https://www.grammy.com/artists/lady-gaga/3611 (last visited May 1, 2025); Corinne Sullivan, *Lady Gaga's 24 Tattoos Legit All Have Fascinating Backstories*, COSMOPOLITAN (July 26, 2024, 2:34 PM), https://www.cosmopolitan.com/entertainment/celebs/g38738659/lady-gaga-tattoos/.

6. *See Olympic Ink: The Tattoos of Team USA*, NBC OLYMPICS, https://www.nbcolympics.com/news/olympic-ink-tattoos-team-usa (Oct. 8, 2021, 8:00 AM).

7. *See Connecticut US Rep. Rosa DeLauro Gets Inked at Age 80 Alongside Her 18-Year-Old Granddaughter*, ASSOCIATED PRESS, https://apnews.com/article/rosa-delauro-tattoo-ea46d0a9b13c2f6a8bfb1267b4a97a61 (July 31, 2023, 4:19 PM); Chris Moody, *'The Tattoo Caucus': Body Art on Capitol Hill*, YAHOO! NEWS (May 8, 2012, 5:47 PM), https://news.yahoo.com/blogs/ticket/tattoo-caucus-body-art-capitol-hill-214754087.html.

opting to go under the tattoo needle.[8] From 2012 to 2019 alone, the number of Americans with tattoos rose by about nine percent,[9] and projections for the global tattoo market are expected to nearly double between the years 2023 and 2030.[10]

Approximately thirty-two percent of Americans have at least one tattoo.[11] Factors like age, gender, race, income, education, religion, and sexual orientation predict one's likelihood of getting "tatted."[12] The number is especially high for younger people, with about forty-one percent of adults under age thirty having at least one tattoo, compared to about thirteen percent of adults aged sixty-five years or above.[13]

As with other permanent decisions involving needles, there are considerations one might take into account when opting to get a tattoo. Some might prioritize an artist's distinctive style, fees, or reputation, while others may first inquire into the artist's or studio's safety practices or any applicable licensing requirements.[14] But there is another question that those considering a tattoo may want to ask: What is in tattoo ink?

8. Mary Whitfill Roeloffs, *Tattoo USA: One-Third of Americans Have Ink As Industry Projected to Hit $4 Billion*, FORBES (Aug. 15, 2023, 4:38 PM), https://www.forbes.com/sites/maryroeloffs/2023/08/15/tattoo-usa-one-third-of-americans-have-ink-as-industry-projected-to-hit-4-billion.

9. *See id.* ("[Twenty-one percent] of people said they had tattoos in 2012 and [thirty percent] said they were inked in 2019."). *See generally* Chris Jackson, *More Americans Have Tattoos Today than Seven Years Ago*, IPSOS (Aug. 29, 2019), https://www.ipsos.com/en-us/news-polls/more-americans-have-tattoos-today.

10. *See* Roeloffs, *supra* note 8.

11. Katherine Schaeffer & Shradha Dinesh, *32% of Americans Have a Tattoo, Including 22% Who Have More Than One*, PEW RSCH. CTR. (Aug. 15, 2023), https://www.pewresearch.org/short-reads/2023/08/15/32-of-americans-have-a-tattoo-including-22-who-have-more-than-one/.

12. *See id.* Thirty-nine percent of Black Americans have at least one tattoo compared to fourteen percent of Asian Americans. *Id.* Education and income level play significant roles in one's likelihood of having a tattoo, with lower formal education or income levels associated with an increased likelihood of having a tattoo. *See id.* Religiously affiliated adults are less likely to have a tattoo, while adults who identify as gay, bisexual, or lesbian have a significantly higher chance of having at least one tattoo. *Id.* Notably, fifty-one percent of gay, bisexual, or lesbian individuals have at least one tattoo, with sixty-eight percent of women in this group having a tattoo. *Id.*

13. *Id.* Gender also plays a significant role, with approximately twenty-seven percent of men having tattoos compared to about 38% of women. *Id.* The number is especially high for young women, with approximately fifty-six percent of women between the ages of eighteen and twenty-nine having at least one tattoo. *Id.*

14. There are many websites for the prospective tattoo recipient offering assistance in picking a tattoo shop or artist. *See, e.g.*, *How to Pick a Tattoo Shop*, WEBMD, https://www.webmd.com/skin-problems-and-treatments/how-to-pick-a-tattoo-shop (last visited May 1, 2025); Ariane Resnick, *9 Tips to Help Choose a Tattoo Artist for Your Best Ink Ever*, BYRDIE (Feb. 10, 2024, 7:00 AM), https://www.byrdie.com/how-to-choose-a-tattoo-artist-8553782; Danny Tress, *Tattoo Studios: 7 Tips for Choosing the Right Shop*, PAINFUL PLEASURES (Sept. 19, 2019),

Not only does the answer to this question likely elude the average American, but also the agency responsible for the regulation of products like tattoo ink, the U.S. Food and Drug Administration ("FDA").[15] The FDA regulates tattoo ink under the categorical umbrella of "cosmetic,"[16] and under this framework, the agency has little premarket authority to assess the composition of tattoo ink and manufacturers have little guidance on how to substantiate product safety.[17] Perpetuating the issue, the FDA declines to use what limited power it has to regulate tattoo ink before it enters the market and the skin of consumers.[18]

Part I of this Note examines the health risks associated with the ingredients and contaminants found in tattoo inks presently on the U.S. market. Part II assesses the powers of the FDA to regulate cosmetics and the implications of this authority for the safety of tattoo ink. Part III takes a look at the European Union's proactive approach to tattoo ink regulation. Part IV compares the FDA's authority to regulate cosmetics with the Environmental Protection Agency's authority to regulate chemicals under the Toxic Substances Control Act and discusses the regulatory overhaul of the Act by way of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Part V provides recommendations for reforming the U.S. cosmetic regulatory framework.

I. HOW TATTOO INK INTERACTS WITH THE BODY AND POSSIBLE HEALTH RISKS OF THE SUBSTANCES FOUND IN TATTOO INKS

With a growing tattooed population, identifying and understanding the ingredients in tattoo inks on the market is imperative for the FDA to protect public health and for consumers to make informed decisions.

https://www.painfulpleasures.com/community/blog/client/tattoo-studios-7-tips-choosing-right-shop/; Paul-Anthony Surdi, *How to Find the Right Tattoo Artist and Tattoo Shop*, TATTOO SCH. (June 29, 2021), https://tattooschool.com/guide-to-choosing-a-tattoo-studio-tattoo-artist/.

15. *See Think Before You Ink: Tattoo Safety*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/think-you-ink-tattoo-safety (Dec. 17, 2024).

16. *Id.*; Alexandria C. Wellman, *Tattoo Ink Is Under-Regulated, Scientists Say*, ABC NEWS (Aug. 24, 2022, 5:59 PM), https://abcnews.go.com/Health/tattoo-ink-regulated-scientists/story?id=88691078.

17. *See infra* Part II.

18. *See infra* Part II.

A. The Composition and Biodistribution[19] of Tattoo Ink

As tattoo ink is permanently embedded in the skin, a look at how the particles interact with the body, both upon injection and over time, is necessary to determine ink safety. Tattoo ink is typically comprised of color pigments that make up the specific color of the ink and a carrier solution that promotes a more even distribution and smoother application of the pigment.[20] The carrier solution comprises about sixty to ninety percent of the tattoo ink volume, while the pigment comprises about ten to forty percent.[21]

Tattoo ink gets applied to the recipient's body through needle pricks that puncture the skin, embedding the ink into the dermis, the skin's middle layer.[22] While the larger particles of the ink stay in place, the body absorbs the smaller particles through the local lymphatic system and blood vessels.[23] The body's exposure to tattoo ink particles may be regarded in two phases: (1) the acute absorption of the carrier solution, and (2) the acute and chronic absorption of the color pigment.[24]

The rate at which the body absorbs the carrier solution is a rapid process, leading to the immediate metabolization of many of the chemicals in the ink.[25] Depending on the ingredients in the ink, the twenty-four hours following tattoo application are usually when the body's most concentrated, or "acute," exposure to the chemicals occurs.[26] While the ingredients in a carrier solution have a "one-time exposure" to the body, the relatively high concentration and rapid absorption of these chemicals may have health consequences for the tattoo recipient.[27]

19. Simply put, "biodistribution" is defined as the tracing of where specific chemical compounds travel in the body. *See Biodistribution*, SCI. DIRECT, https://www.sciencedirect.com/topics/medicine-and-dentistry/biodistribution (last visited May 1, 2025).

20. *See Exposing What's in Tattoo Ink*, AM. CHEM. SOC'Y (Aug. 24, 2022), https://www.acs.org/pressroom/newsreleases/2022/august/exposing-whats-in-tattoo-ink.html; *Chemistry of Tattoo Ink*, PREMIUM TATTOO REMOVAL, https://www.premiumtattooremoval.com/chemistry-of-tattoo-ink (last visited May 1, 2025).

21. *See Research on Potential Long-Term Health Effects of Tattooing*, WORLD HEALTH ORG., https://tattoo.iarc.who.int/background/ (last visited May 1, 2025).

22. *See* Amanda Onion, *What Happens to Tattoo Ink After It's Injected into Your Skin?*, LIVE SCI. (Sept. 25, 2017), https://www.livescience.com/60503-tattoo-ink-body.html.

23. *See id.*

24. *See Research on Potential Long-Term Health Effects of Tattooing*, *supra* note 21.

25. *See id.*

26. *Id.*

27. *Id.* ("[A]cute exposures may give rise to irreversible DNA mutations, and any acute or chronic exposure to these substances may increase the individual's lifelong risk of developing cancer.").

In addition to the carrier solution, the tattoo recipient will experience acute and chronic exposure to the ink pigment.[28] While the pigment is meant to remain in the skin to maintain the aesthetic of the tattoo,[29] factors like exposure to ultraviolet light or certain bacteria can degrade these pigment particles over time.[30] Like the particles that comprise the carrier solution, once the pigment particles degrade, they are absorbed by nearby lymphatic and blood vessels.[31]

Recently, scientists have discovered that tattoo ink pigment can travel through the body in "nano-form"[32] and accumulate in the lymph nodes, which may become enlarged and discolored, taking on the hue of the pigment particle.[33] While the interaction between the pigment particles and the human body is not fully understood, scientists are concerned that the enlargement of the lymph nodes can lead to prolonged exposure.[34]

Though pigment particles from tattoos have conclusively been found in the lymph nodes, the extent to which tattoo ink particles travel further in the body remains unclear in humans.[35] However, testing done on animals revealed pigment particles could travel extensively in the body.[36] The study showed substances like "[t]itanium dioxide[,] . . . in the liver, spleen, and lungs, and red and black tattoo ink particles were found in the liver."[37] If tattoo ink behaves similarly within the human body, this research is concerning, as it suggests vital organs may be exposed to the largely unregulated and mysterious substances that comprise commercial tattoo inks.[38] Thus, protecting consumers and their ability to make informed choices requires transparency about the ingredients in tattoo inks and the risks they pose to human health.

28. *See id.*
29. *See* Onion, *supra* note 22.
30. *Exposing What's in Tattoo Ink*, *supra* note 20.
31. *See Research on Potential Long-Term Health Effects of Tattooing*, *supra* note 21.
32. *See* European Synchrotron Radiation Facility, *Nanoparticles from Tattoos Travel Inside the Body, Scientists Find*, SCI. DAILY (Sept. 15, 2017), https://www.sciencedaily.com/releases/2017/09/170912093105.htm; *Nanoparticle*, SCI. DIRECT, https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/nanoparticle (last visited May 1, 2025) ("Nanoparticles are spherical, polymeric particles composed of natural or artificial polymers.").
33. European Synchrotron Radiation Facility, *supra* note 32.
34. *Id.*
35. *See Research on Potential Long-Term Health Effects of Tattooing*, *supra* note 21.
36. *See id.*
37. *Id.*
38. *See id.*

B. Ingredients in Traditional Tattoo Inks and Potential Health Risks

Between the ingredients comprising the carrier solution and the color pigment, tattoo ink can contain up to one hundred different chemicals.[39] Of the chemicals commonly found in tattoo ink, many have been identified by research groups, governing bodies, and international organizations as presenting an array of associated health risks.[40]

Through its International Agency for Research on Cancer ("IARC") Monographs program,[41] the World Health Organization ("WHO") has *consistently* identified known, probable, and possible carcinogens in tattoo ink.[42] WHO has found many chemicals in tattoo ink to be directly genotoxic,[43] meaning that the chemicals can damage DNA.[44] Acute exposure to these chemicals may lead to permanent mutations of the DNA, and both chronic and acute chemical exposure may increase the tattoo recipient's risk of cancer.[45]

Typical carrier solutions are made up of solvents like ethyl alcohol or distilled water,[46] in addition to additives with varying purposes like preserving, sterilizing, or maintaining an adequate ink consistency.[47] While some ingredients comprising carrier solutions pose little risk to human health,[48] researchers have identified several frequently unlabeled substances that raise safety concerns.[49]

39. *Id.*

40. *Id.*

41. *Id.* "The IARC Monographs Programme identifies and evaluates the preventable causes of cancer in humans. Since 1971, more than 1000 agents have been evaluated." WORLD HEALTH ORG., IARC MONOGRAPHS ON THE IDENTIFICATION OF CARCINOGENIC HAZARDS TO HUMANS, QUESTIONS AND ANSWERS 1 (2019), https://monographs.iarc.who.int/wp-content/uploads/2018/07/IARCMonographs-QA.pdf.

42. *Research on Potential Long-Term Health Effects of Tattooing*, *supra* note 21.

43. *Id.*

44. *Genotoxic*, SCI. COMMS., https://ec.europa.eu/health/scientific_committees/opinions_layman/en/electromagnetic-fields/glossary/ghi/genotoxic-genotoxicity.htm (last visited May 1, 2025). DNA is "the molecule that carries genetic information for the development and functioning of an organism." Sarah A. Bates, *Deoxyribonucleic Acid (DNA)*, NAT'L HUM. GENOME RSCH. INST., https://www.genome.gov/genetics-glossary/Deoxyribonucleic-Acid-DNA (Nov. 25, 2025).

45. *Research on Potential Long-Term Health Effects of Tattooing*, *supra* note 21.

46. *Id.* The "solvent" is the primary liquid in which the other ingredients dissolve to form the tattoo ink solution. *See Solvent*, BRITANNICA, https://www.britannica.com/science/solvent-chemistry (Nov. 19, 2025).

47. *See Chemistry of Tattoo Ink*, *supra* note 20.

48. *Id.*

49. *Id.*

For example, formaldehyde and formaldehyde-releasing preservatives are commonly found in tattoo ink.[50] Formaldehyde is a chemical compound that can cause health issues ranging from skin irritation to certain types of cancer at different levels of exposure.[51] In fact, due to its cancer-causing risks, the European Union ("EU") has banned the inclusion of formaldehyde in many products, including tattoo inks.[52] In a study that scrutinized 127 tattoo inks available on the market, seventy-three percent contained formaldehyde-emitting ingredients.[53] Save for one exception, every brand in the survey had at least one ink product implicated in releasing formaldehyde.[54]

Like the carrier solutions, the pigments found in tattoo ink may come with potential health risks. For example, these pigments can contain heavy metals such as cadmium, lead, mercury, antimony, beryllium, and arsenic.[55] With adequate exposure, these metals have been associated with various types of cancer, neurodegenerative diseases, cardiovascular issues, and gastrointestinal disorders.[56] In addition to heavy metals, the presence of polycyclic aromatic hydrocarbons ("PAHs") in tattoo ink pigments is concerning, as these chemicals are known carcinogens[57] and can travel from the skin to the lymph nodes.[58] PAHs are commonly

50. *See* Yujie Linda Liou et al., *Formaldehyde Release from Predispersed Tattoo Inks: Analysis Using the Chromotropic Acid Method*, 32 DERMATITIS 327, 327–28 (2021).

51. *Facts About Formaldehyde*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/formaldehyde/facts-about-formaldehyde (July 7, 2025). While preservatives that release formaldehyde may not directly cause cancer, the formaldehyde released from preservatives "has been linked to cancer." *Formaldehyde and Formaldehyde-Releasing Preservatives*, CAMPAIGN FOR SAFE COSMS., https://www.safecosmetics.org/chemicals/formaldehyde/ (last visited May 1, 2025); Liou et al., *supra* note 50, at 328 (discussing reports of dermatitis in connection with exposure to tattoo inks containing formaldehyde).

52. *See* 2022 O.J. (L 184) 3.

53. Liou et al., *supra* note 50, at 327.

54. *Id.* The study found no correlation between formaldehyde release and ink color. *Id.*

55. *See* Sandeep Negi et al., *Tattoo Inks Are Toxicological Risks to Human Health: A Systematic Review of Their Ingredients, Fate Inside Skin, Toxicity Due to Polycyclic Aromatic Hydrocarbons, Primary Aromatic Amines, Metals, and Overview of Regulatory Frameworks*, 38 TOXICOLOGY & INDUS. HEALTH 417, 417 (2022); Mayyadah S. Abed et al., *Heavy Metals in Cosmetics and Tattoos: A Review of Historical Background, Health Impact, and Regulatory Limits*, 13 J. HAZARDOUS MATERIALS ADVANCES, Feb. 2024, at 1, 1–2.

56. *See* Negi et al., *supra* note 55, at 417.

57. *Id.* at 421; *see Does Tattoo Ink Give You Cancer?*, CANCER COUNCIL, https://www.cancer.org.au/iheard/does-tattoo-ink-give-you-cancer (last visited May 1, 2025). *See generally* Karin Lehner et al., *Black Tattoos Entail Substantial Uptake of Genotoxicpolycyclic Aromatic Hydrocarbons (PAH) in Human Skin and Regional Lymph Nodes*, 9 PLOS ONE 1 (2014).

58. *See* Sarah Everts, *What Chemicals Are in Your Tattoo?*, CHEM. & ENG'G NEWS (Aug. 15, 2016), https://cen.acs.org/articles/94/i33/chemicals-tattoo.html.

included in black inks "and are most likely impurities from industrial production."[59]

Similar to PAHs, the use of azo pigments in tattoo ink may be problematic.[60] Azo pigments comprise approximately sixty percent of the dyes found in tattoo inks.[61] When chemically intact, azo pigments pose little risk to human health.[62] However, exposure to ultraviolet light or bacteria can degrade azo pigments over time into primary aromatic amines ("PAAs").[63] Like PAH's, PAAs are also known for their carcinogenic potential.[64]

C. Contaminated Tattoo Ink

Contaminants are commonly found in commercial tattoo inks and may pose health risks to tattoo recipients.[65] A microbiological survey revealed contamination in a significant number of tattoo and permanent makeup inks.[66] The survey examined eighty-five unopened inks representing thirteen different tattoo ink manufacturers.[67] Nearly half of those inks tested contained microorganisms.[68] Of the eighty-five inks tested, thirty-three were contaminated with bacteria, two inks contained fungi, and seven inks contained both bacteria and fungi.[69]

The U.S. Centers for Disease Control and Prevention ("CDC") has reported public health concerns regarding microorganisms found in tattoo ink.[70] For example, the CDC connected tattoo inks contaminated

59. *Id.* One example, benzo(a)pyrene, is a PAH commonly found in ink containing carbon black pigments. *See* Negi et al., *supra* note 55, at 418.

60. *See* Negi et al., *supra* note 55, at 421. *See generally* Everts, *supra* note 58.

61. Everts, *supra* note 58.

62. *Id.*; *Exposing What's in Tattoo Ink*, *supra* note 20.

63. *Exposing What's in Tattoo Ink*, *supra* note 20.

64. *See* Negi et al, *supra* note 55, at 421.

65. *See Think Before You Ink: Tattoo Safety*, *supra* note 15. The FDA issued draft guidance in June 2023 "to help tattoo ink manufacturers and distributors recognize and prevent situations where contamination can occur." *Id.* These contaminants include "bacteria, mold, or other microorganisms." *Id.*

66. S.W. Nho et al., *Microbiological Survey of Commercial Tattoo and Permanent Makeup Inks Available in the United States*, 124 J. APPLIED MICROBIOLOGY 1294, 1294 (2018). Permanent makeup, also known as micropigmentation, is a form of tattoo application "used to improve or replace lost coloring on [the] skin" and is typically applied to areas like the eyelids, lips, or eyebrows. *Micropigmentation*, CLEV. CLINIC, https://my.clevelandclinic.org/health/treatments/11004-micropigmentation (July 2, 2020).

67. Nho et al., *supra* note 66, at 1294.

68. *See id.*

69. *Id.*

70. *See Tattoo-Associated Nontuberculous Mycobacterial Skin Infections — Multiple States, 2011–2012*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 24, 2012), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6133a3.htm ("NTM contamination of

with microorganisms to outbreaks of nontuberculous mycobacterial ("NTM") skin infections.[71] Common with these infections are symptoms like persistent and painful rashes, boils, and blistering of the skin.[72] NTM skin infections are challenging to diagnose,[73] and recovery is often lengthy, as first identifying the organism can "take up to [six] weeks"[74] and the recommended treatment typically lasts between two to four months.[75]

D. New Ink

In addition to health risks posed by tattoo inks traditionally used in the United States, emerging ink technologies[76] create new concerns. For example, ultraviolet or "glow-in-the-dark" tattoos have become a trend over the last few years.[77] These tattoos are only shown on the body when under blacklight and are applied by injecting a "special ink" that produces a glowing effect.[78]

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inks can occur during the manufacturing process as a result of using contaminated ingredients or poor manufacturing practices, or when inks are diluted with nonsterile water by tattoo artists.").

71. *See id.* In the span of a year, the CDC found outbreaks of NTM skin infections across numerous states. *See id.* After state and federal investigations of the outbreaks, the CDC determined that "[t]he use of ink contaminated before distribution or just before tattooing likely led to [the] infections." *Id.*

72. *See Nontuberculous Mycobacteria Infections*, CLEV. CLINIC, https://my.clevelandclinic.org/health/diseases/21200-nontuberculous-mycobacteria-infections (Feb. 19, 2024); *Tattoo-Associated Nontuberculous Mycobacterial Skin Infections — Multiple States – 2011–2012*, *supra* note 70.

73. Pamela M. LeBlanc et al., *Tattoo Ink–Related Infections — Awareness, Diagnosis, Reporting, and Prevention*, 367 NEW ENG. J. MED. 985, 986 (2012). An NTM skin infection can be challenging to diagnose as it's commonly confused with allergies and other skin conditions. *Id.*

74. *See id.*

75. Xin-Yu Wang et al., *Treatment of Non-Tuberculosis Mycobacteria Skin Infections*, 14 FRONTIERS PHARMACOLOGY 1, 6 (2023). The specific susceptibility profile of the involved NTM species constrains the options for treating infections caused by NTM. LeBlanc et al., *supra* note 73, at 986. In addition, there is the potential for concurrent infection with other pathogenic organisms, like methicillin-resistant Staphylococcus aureus ("MRSA"), which may present more challenges to the treatment regimen and impede recovery. *Id.*

76. *See, e.g.*, *All You Need to Know About Black Light Tattoos, According to Tattoo Artists*, INKED MAG. (Jan. 2, 2019), https://inkedmag.com/original-news/black-light-tattoos-uv-ink-guide.

77. *See id.*; *Glow Up Your Ink: Everything You Need to Know About UV Light Tattoos,* INK ADDICT (Jan. 9, 2024), https://inkaddict.com/blogs/default-blog/glow-up-your-ink-everything-you-need-to-know-about-uv-light-tattoos.

78. *UV Tattoos: Application & Risks*, TATTOOHEALTH.ORG, https://www.tattoohealth.org/content/tattoo-ink/uv-tattoos-ultraviolet-tattoo-ink-health-risks (last visited May 1, 2025).

Ultraviolet tattoos produce higher reports of adverse physical reactions when compared to tattoos created with more traditional inks.[79] Many of the reported health concerns from these "special inks" are connected to the presence of chemicals, like phosphorus, not typically found in traditional inks.[80] Phosphorus is associated with health issues like "severe blistering, pain, burning sensations, and . . . skin rashes."[81]

E. A Note on Dose and Mislabeled Products

Commercial tattoo inks contain numerous alarming ingredients and contaminants, but it is important to remember a fundamental principle of toxicology: "The dose makes the poison."[82] Simply put, knowing the quantity and extent of exposure to a substance in tattoo ink is necessary to determine the level of risk it poses to human health.[83] Yet to accurately assess the risk, both regulators and consumers must first know what substances are actually present in the ink, a task made difficult by widespread mislabeling.[84]

In a recent study of fifty-four tattoo inks sold on the U.S. market, "[forty-five] contained pigments or additives that manufacturers did not list on the ingredient label."[85] For instance, although unlisted, approximately fifty percent of the inks contained polyethylene glycol, a potential organ toxicant, and around thirty percent contained propylene glycol, a known allergen.[86]

While the law requires manufacturers to report the ingredients in tattoo inks to the FDA, "little has been done to determine the composition of tattoo inks in the United States market."[87] This lack of transparency and ingredient verification denies consumers the ability to give informed consent or make educated decisions about what substances they introduce to their bodies.

79. *Id.*

80. *See id.*

81. *Id.*

82. *"The Dose Makes the Poison"*, CHEMICALSAFETYFACTS.ORG (Aug. 17, 2022), https://www.chemicalsafetyfacts.org/health-and-safety/the-dose-makes-the-poison/; Gina Hilton, *The Dose Makes the Poison*, N.C. STATE UNIV.: CTR. FOR HUMAN HEALTH & THE ENV'T (Jan. 4, 2016), https://chhe.research.ncsu.edu/the-dose-makes-the-poison/.

83. *See* sources cited *supra* note 82.

84. Krystal Vasquez, *Tattoo Inks May Not Be What the Label Says They Are*, CHEM. & ENG'G NEWS (Mar. 11, 2024), https://cen.acs.org/analytical-chemistry/Tattoo-inks-label-says/102/web/2024/03.

85. *Id.*

86. *Id.* Fun Fact: In 2018, the American Contact Dermatitis Society awarded propylene glycol the title "Allergen of the Year." *Id.*

87. Kelli Moseman et al., *What's in My Ink: An Analysis of Commercial Tattoo Ink on the US Market*, 96 ANALYTICAL CHEM. 3906, 3907 (2024).

II. LIMITATIONS ON THE FDA'S PREMARKET REGULATION OF TATTOO INK: PITFALLS OF THE COSMETICS REGULATORY FRAMEWORK

The prevalence of potentially harmful and often unlabeled ingredients and contaminants found in tattoo inks on the market sheds light on the inadequacies of the legal framework under which tattoo ink is regulated. While state and local jurisdictions regulate the tattooing *process*, the FDA is responsible for regulating *tattoo ink* and does so under its cosmetics framework.[88]

Under this framework, the FDA lacks the authority to effectively determine the safety or accuracy of many of the ingredients in tattoo ink *before* the ink enters the skin of consumers.[89] Although a recent reform brought important updates to this framework,[90] the FDA's limited premarket authority largely remains.[91] Compounding this issue are weak safety standards[92] and reliance on industry self-regulation.[93] And, perhaps most frustratingly, the FDA fails to use the limited premarket authority it does have to regulate tattoo ink.[94] These deficiencies create challenges for ensuring consumer safety, especially given the unique permanence of tattoo ink.[95]

A. Where the FDA Draws Its Power and Recent Reform to the Cosmetics Regulatory Scheme

The FDA draws its regulatory authority over cosmetics from the Federal Food, Drug, and Cosmetic Act ("FDCA") of 1938.[96] The FDCA prohibits the "[a]dulteration" and "[m]isbranding" of cosmetics in interstate commerce.[97] A cosmetic is adulterated if it contains "any poisonous or deleterious substance" that makes it "injurious . . . under

88. *See Think Before You Ink: Tattoo Safety*, *supra* note 15.
89. *See supra* Section II.B.
90. *See supra* Section II.A.
91. *See supra* Section II.B.
92. *See id.*
93. *See supra* Section II.C.
94. *See supra* Section II.D.
95. *See id.*
96. *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. 3, 2022).
97. *Id.*; *see* NORA WELLS, CONG. RSCH. SERV., R47826, FDA REGULATION OF COSMETICS AND PERSONAL CARE PRODUCTS UNDER THE MODERNIZATION OF COSMETICS REGULATION ACT OF 2022 (MoCRA) 11 (2023), https://www.congress.gov/crs_external_products/R/PDF/R47826/R47826.3.pdf.

the conditions of use prescribed in the labeling thereof."[98] In addition to the FDCA, the FDA derives its power to regulate cosmetics labeling from the Fair Packaging and Labeling Act ("FPLA").[99] Under the FDCA and the FPLA, a cosmetic is misbranded if its "labeling is false or misleading," and a product may be misbranded if it fails to "provide material facts" like "directions for safe use" or "warning statements."[100]

In the eighty years following the enactment of the FDCA, the cosmetics framework stood largely unchanged; however, the delay was not for a lack of trying.[101] Since the 1950s, members of Congress have attempted to amend the FDCA, but because of industry pushback, these attempts mostly failed.[102] But finally, in December 2022, Congress passed the Modernization of Cosmetics Regulation Act ("MoCRA").[103]

Because of MoCRA, cosmetics manufacturers must register their facilities and provide lists of cosmetic products and some labeling information to the FDA.[104] Under MoCRA, the FDA is now set to establish and enforce final "Good Manufacturing Practice" regulations, mandate disclosure of significant adverse events of cosmetic products on consumer health, and, importantly, the FDA now has the power to mandate the recall of adulterated or misbranded cosmetics on the market.[105]

Despite some important and long-overdue updates to the cosmetics regulatory framework, MoCRA largely maintains the status quo for the FDA's premarket powers. Manufacturers need not seek ingredient approval before selling their cosmetics on the U.S. market,[106] and apart

98. *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, But Are FDA-Regulated, supra* note 96.

99. *Id.*; *Cosmetics Labeling*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/cosmetics-labeling (Nov. 3, 2022).

100. *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, But Are FDA-Regulated, supra* note 96. By releasing an adulterated or misbranded cosmetic product into interstate commerce, manufacturers could face criminal penalties. *Cosmetics Labeling*, *supra* note 99.

101. *See* Scott Faber, *80 Years Later, Cosmetics Chemicals Still Unregulated*, EWG (June 25, 2018), https://www.ewg.org/news-insights/news/80-years-later-cosmetics-chemicals-still-unregulated.

102. *See id.*

103. *See* Consolidated Appropriations Act of 2023, H.R. 2617, 117th Cong. §§ 3501–08 (2022) (enacted) (codified as amended in scattered sections of 21 U.S.C.).

104. *See id.*

105. *See id.*

106. *Small Businesses & Homemade Cosmetics: Fact Sheet*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/resources-industry-cosmetics/small-businesses-homemade-cosmetics-fact-sheet (Sept. 29, 2023) ("The law does not require cosmetic products and ingredients, except for color additives, to be approved by FDA before they go on the market.").

from color additives,[107] the FDA has no authority to independently evaluate the safety of ingredients before cosmetics reach consumers.[108] Though the FDA has long maintained that manufacturers must ensure the safety of their cosmetic products, this responsibility was not statutorily mandated until MoCRA.[109]

Despite MoCRA's codification of a safety substantiation requirement, some have criticized the law for codifying a weaker standard than that put forth by prior FDA regulations.[110] For example, MoCRA requires cosmetics manufacturers to demonstrate product safety under "customary or usual" uses.[111] However, present FDA regulations require an additional consideration of "reasonably expected related uses."[112] This standard set forth by MoCRA seems to supersede the FDA's regulations and reduce the standard for claims of product safety substantiation.[113] Furthermore, although manufacturers must now maintain records to support claims of substantiated product safety, MoCRA does not require the FDA to review those records.[114]

Concerningly, neither MoCRA nor FDA regulations establish clear guidelines regarding what constitutes sufficient testing or evidence to demonstrate product or ingredient safety.[115] MoCRA simply states that "adequate substantiation of safety" is shown through "tests" or "evidence" that qualified experts or scientists consider "sufficient to support a reasonable certainty that a cosmetic product is . . . not injurious" when

107. *See Color Additives and Cosmetics: Fact Sheet*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/color-additives-specific-products/color-additives-and-cosmetics-fact-sheet (June 28, 2022).

108. *See FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, But Are FDA-Regulated, supra* note 96.

109. WELLS, *supra* note 97, at 6.

110. *See, e.g.*, JANET NUDELMAN, MODERNIZATION OF COSMETICS REGULATION ACT OF 2022 (MOCRA): SECTION-BY-SECTION ANALYSIS 3–4 (2023) (providing a section-by-section review of MoCRA); Anh-Thi Le, *French-Tipped Formaldehyde: Why FDA's Statutory Framework Enables Toxic Chemical Exposures in Manicure Products; How Rulemaking or Congressional Action Can Curb Its Detrimental Effect on Occupational Health,* 75 ADMIN. L. REV. 393, 405–06 (2023).

111. Le, *supra* note 110, at 405.

112. *Id.*

113. *Id.* at 405–406.

114. *See* Monica Amarelo, *Reforming Federal Cosmetics Law: What Is the Modernization of Cosmetics Regulation Act?*, EWG (Dec. 22, 2023), https://www.ewg.org/news-insights/news/2023/12/reforming-federal-cosmetics-law-what-modernization-cosmetics-regulation.

115. *See* Magda Patitsas et al., *MoCRA: Updates to FDA Safety Substantiation Requirements*, HUSCH BLACKWELL (Aug. 24, 2023), https://www.productlawperspective.com/2023/08/mocra-updates-to-fda-safety-substantiation-requirements/.

used in a way that is "customary or usual."[116] The FDA has provided that cosmetics manufacturers can substantiate safety by relying on "available toxicological test data" for ingredients and similar products, and by performing further "toxicological and other tests that are appropriate in light of such existing data."[117] However, without standardized benchmarks for safety verification, cosmetics manufacturers can minimize the potential risks posed by the ingredients in their products before marketing.[118]

B. Self-Regulation: A Conflict of Interest

Leaving safety substantiation up to the cosmetics industry poses a serious conflict of interest. For instance, with member companies that "represent more than [ninety percent] of the U.S. beauty industry," the Personal Care Products Council ("PCPC") is the largest cosmetics trade association in the United States.[119] In addition to being the "lobbying arm of the beauty industry,"[120] the PCPC maintains a firm grasp on the *only* U.S. panel responsible for assessing the safety of cosmetic ingredients, the Cosmetic Ingredient Review ("CIR").[121]

116. Consolidated Appropriations Act of 2023, H.R. 2617, 117th Cong. §§ 3501–08 (2022) (enacted) (codified as amended in scattered sections of 21 U.S.C.); *see also* Le, *supra* note 110, at 404–05.

117. *FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved*, *But Are FDA-Regulated, supra* note 96 (quoting Food, Drug, and Cosmetic Products: Warning Statements, 40 Fed. Reg. 8912, 8916 (Mar. 3, 1975)).

118. *See* Le, *supra* note 110, at 405–06.

119. ALEXANDRA SCRANTON, INDUSTRY-FUNDED COSMETICS SAFETY PANEL FAILS TO PROTECT PUBLIC HEALTH AND THE ENVIRONMENT 1 (2018); *About PCPC*, PERS. CARE PRODS. COUNCIL, https://www.personalcarecouncil.org/about-us/ (last visited May 1, 2025). The PCPC is comprised of 600 members, including cosmetics manufacturers and distributors in addition to "[s]uppliers of ingredients, raw materials, packaging and other services." *Member Companies*, PERS. CARE PRODS. COUNCIL, https://www.personalcarecouncil.org/about-us/member-companies/ (last visited May 1, 2025).

120. Victoria St. Martin, *A New Law Regulating the Cosmetics Industry Expands the FDA's Power but Fails to Ban Toxic Chemicals in Beauty Products*, INSIDE CLIMATE NEWS (Nov. 27, 2023), https://insideclimatenews.org/news/27112023/dereliction-of-beauty-part-two/; *see also Client Profile: Personal Care Products Council*, OPEN SECRETS, https://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2023&id=D000028328 (last visited May 1, 2025) (displaying the total lobbying expenditures of the PCPC in 2023).

121. *See About the Cosmetic Ingredient Review*, COSM. INGREDIENT REV., https://www.cir-safety.org/about (last visited May 1, 2025); Le, *supra* note 110, at 398; *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 (stating that the PCPC's funding of the CIR "creates a substantial conflict of interest").

The CIR comprises scientists who assess ingredient safety by examining accessible data from cosmetics manufacturers.[122] Subsequently, those cosmetics manufacturers rely on the CIR findings to support their claims of ingredient safety.[123] The PCPC not only established the CIR, but it continues to both fund and staff it.[124]

Though they claim independence from one another,[125] there is an undeniable conflict presented by the CIR's ties to the PCPC.[126] Of particular concern, some CIR findings conflict with the findings of neutral government entities,[127] and notably, in the over thirty-five years since its founding, the CIR has identified merely eleven ingredients unsafe for use in cosmetics.[128] Thus, serious doubt is cast on the legitimacy of the CIR's ingredient safety determinations.

C. Untapped Power: The Color Additive Exception

The FDA's regulatory authority over cosmetics is limited, as neither cosmetic products nor ingredients are subject to FDA approval before entering commerce.[129] However, an exception to this rule arose from the enactment of the Color Additive Amendments Act of 1960, which provides special regulations for color additives in cosmetics.[130]

122. *See How Does CIR Work?*, COSM. INGREDIENT REV., https://www.cir-safety.org/how-does-cir-work (last visited May 1, 2025).

123. *See Product Testing of Cosmetics*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/cosmetics-science-research/product-testing-cosmetics (Nov. 21, 2022) (stating that manufacturers can use available data from the CIR to support ingredient safety substantiation claims).

124. *See Do You Know What's in Your Cosmetics?*, *supra* note 121.

125. *See, e.g.*, *Expert Panel for Cosmetic Ingredient Safety*, PERS. CARE PRODS. COUNCIL, https://www.personalcarecouncil.org/science-safety/cosmetic-ingredient-review/ (last visited May 1, 2025); *Do You Know What's in Your Cosmetics?*, *supra* note 121; *see also Product Testing of Cosmetics*, *supra* note 123 (although the FDA participates in CIR meetings, the agency does not partake in any votes by the panel).

126. *See, e.g.*, St. Martin, *supra* note 120; *Do You Know What's in Your Cosmetics?*, *supra* note 121; SCRANTON, *supra* note 119, at 1.

127. *See Do You Know What's in Your Cosmetics?*, *supra* note 121 ("[S]ome of the panel's conclusions have been at odds with those of impartial government entities . . . ."). For example, the CIR declared specific parabens safe, though the same parabens have been restricted by the European Union due to their endocrine-disrupting potential. *See* SCRANTON, *supra* note 119, at 5–6.

128. *See* COSMETIC INGREDIENT REVIEW, INGREDIENTS FOUND UNSAFE FOR USE IN COSMETICS (11 TOTAL, THROUGH FEBRUARY, 2012) 1 (2012); *see also* Le, *supra* note 110, at 403–04 (discussing the CIR's finding of only eleven unsafe cosmetic ingredients).

129. *See FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, But FDA-Regulated*, *supra* note 96.

130. *See Color Additives History*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/color-additives/color-additives-history (Nov. 3, 2017); *see also*

A color additive is defined as "any . . . dye, pigment, or other substance . . . that, when added or applied to a . . . cosmetic or to the human body or any part thereof, is capable . . . of imparting a color thereto."[131] With few exceptions, the FDA is required to approve and regulate the inclusion of color additives in cosmetics.[132] The agency must create regulations pertaining to matters like color additive identification, intended use, and the maximum allowable concentration.[133] After approval, the FDA must batch-certify certain colors before they can be used in cosmetics.[134]

Color additives are prohibited from inclusion in a product unless those colors are explicitly approved for that product's intended use.[135] For example, a color additive approved for only "external use"[136] may be included in a product like body lotion but not in a product like toothpaste.[137] Thus, any color additive in a cosmetic product intended for injection into the skin must be approved specifically for that purpose.[138]

Under this framework, any color additive in tattoo ink is subject to premarket approval by the FDA. And yet, though tattoo inks certainly contain color additives,[139] the FDA has not approved *any* color additives for injection into the skin.[140] The FDA explains that "because of other competing public health priorities and a previous lack of evidence of safety problems specifically associated with these pigments, [the] FDA traditionally has not exercised regulatory authority for color additives on the pigments used in tattoo inks."[141] Thus, even with the authority to determine the safety of a typical component of tattoo ink, color pigment, the FDA fails to act.

FDA Authority Over Cosmetics: How Cosmetics Are Not FDA-Approved, But Are FDA-Regulated, supra note 96.

131. 21 C.F.R. § 70.3(f) (1996).

132. *See Color Additives and Cosmetics: Fact Sheet*, *supra* note 107.

133. *See id.*

134. *Id.*

135. *Color Additives and Cosmetics: Fact Sheet*, *supra* note 107.

136. When a cosmetic is approved for "external use," the FDA has approved it for application "only to external parts of the body and not to the lips or any body surface covered by mucous membrane." 21 C.F.R. § 70.3(v) (1996).

137. *See How Safe are Color Additives?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/how-safe-are-color-additives (July 13, 2023).

138. *Color Additives and Cosmetics: Fact Sheet*, *supra* note 107.

139. *See supra* Section I.A (discussing the composition of tattoo ink).

140. *See Color Additives and Cosmetics: Fact Sheet*, *supra* note 107.

141. *Tattoos & Permanent Makeup: Fact Sheet*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/cosmetics/cosmetic-products/tattoos-permanent-makeup-fact-sheet (Oct. 15, 2024).

D. The Reality of Reaction

MoCRA strengthens consumer protection by authorizing the FDA to recall misbranded and adulterated cosmetics from the market;[142] however, this reactive design means FDA action may follow consumer harm instead of proactively preventing it. Specifically for a product like tattoo ink, this gap in protection becomes even more pronounced. Whereas with other kinds of cosmetics, consumers have a choice to discontinue use,[143] there is no such option for tattoo ink already embedded in the skin.[144]

In fact, a tattoo recipient's attempt to "discontinue" use of tattoo ink already injected into their skin could actually expose them to even more of the substance at issue.[145] For example, one way to remove a tattoo is by way of a laser procedure that targets tattoo ink pigment particles with intense beams of light, heating and breaking them down into smaller fragments.[146] This process is intended to facilitate the body's natural mechanisms for eliminating foreign particles,[147] meaning the acute absorption of the ink's color pigment,[148] resulting in a concentrated exposure to any of the remaining substances in the ink.[149]

III. AN ALTERNATE REALITY: A GLANCE AT THE EUROPEAN UNION'S PROACTIVE APPROACH TO REGULATION

The United States' current framework for cosmetics regulation is characterized by action taken in response to harm, effectively turning consumers into guinea pigs. Unlike this framework, the EU has implemented a comprehensive preventative strategy for regulating the

142. *See* Consolidated Appropriations Act of 2023, H.R. 2617, 117th Cong. §§ 3501–08 (2022) (enacted) (codified as amended in scattered sections of 21 U.S.C.).

143. For example, a consumer who has an adverse reaction to a certain lipstick product has the option to discontinue using that product.

144. *See* Onion, *supra* note 22. Consumers can suffer delayed complications from a tattoo. *See* Vanessa Ngan, *Tattoo-Associated Skin Reactions*, DERMNET, https://dermnetnz.org/topics/tattoo-associated-skin-reactions (Nov. 2019) (describing an ailment resulting from a "delayed hypersensitivity reaction to tattoo pigment").

145. *See Tattoos: Even Parting with Them is Not Without Risks*, BFR (Aug. 17, 2015), https://www.bfr.bund.de/en/press-release/tattoos-even-parting-with-them-is-not-without-risks/.

146. *See Tattoo Removal*, CLEV. CLINIC, https://my.clevelandclinic.org/health/treatments/8313-tattoo-removal (Dec. 9, 2022).

147. *See id.*

148. *See supra* Section I.A.

149. *See Tattoos: Even Parting with Them is Not Without Risks* , *supra* note 145.

substances found in products like tattoo ink.[150] The EU's regulatory framework exemplifies a highly proactive approach to regulation and provides insight into the potential impacts on industry and response therefrom when such an approach is taken.

A. How the EU Regulates Tattoo Ink

In the EU, the substances found in products like tattoo ink are regulated under a more general framework of chemical regulation.[151] The main regulatory mechanism is the Registration, Evaluation, Authorization, and Restriction of Chemicals ("REACH") Regulation.[152] Under REACH, chemicals in tattoo ink need to be registered, evaluated, and approved *before* being placed on the market.[153]

The EU has taken significant steps to address the risks associated with the substances found in tattoo inks.[154] After investigating the known and potentially toxic chemicals comprising tattoo ink,[155] safer alternatives, and the socio-economic impact of chemical restrictions, the European Chemicals Agency ("ECHA")[156] proposed recommendations for chemical limitations in tattoo ink.[157] As a result of ECHA's findings, in January 2022, the EU limited the use of thousands of chemicals in commercial tattoo ink through the REACH Regulation.[158]

150. *See Understanding REACH*, EUR. CHEMS. AGENCY, https://echa.europa.eu/regulations/reach/understanding-reach (last visited May 1, 2025).

151. *See id.*

152. *Id.*

153. *See id.*

154. *See Tattoo Inks and Permanent Make-Up*, EUR. CHEMS. AGENCY, https://echa.europa.eu/hot-topics/tattoo-inks (last visited May 1, 2025).

155. The EU paid attention particularly to "chemicals that are carcinogenic, mutagenic and toxic to reproduction (CMRs); sensitisers, irritants and corrosive to the skin; substances that are corrosive or damaging to the eye; metals; and other substances in the *Council of Europe's resolution on requirements and criteria for the safety of tattoos and permanent make-up*." *Id.* (emphasis in original).

156. The European Chemicals Agency is responsible for implementing the EU's chemical laws. *European Chemicals Agency (ECHA)*, EUR. UNION, https://european-union.europa.eu/institutions-law-budget/institutions-and-bodies/search-all-eu-institutions-and-bodies/european-chemicals-agency-echa_en (last visited May 1, 2025).

157. *Tattoo Inks and Permanent Make-Up*, *supra* note 154.

158. *See id.* Some of these chemicals include "azodyes, carcinogenic aromatic amines, polycyclic aromatic hydrocarbons . . . metals and methanol." *Id.*

B. Industry Backlash

Not everyone is happy about the EU's proactive approach to tattoo ink regulation.[159] Perhaps predictably, members of the tattooing industry argue that REACH's sweeping chemical bans detrimentally impact business and the prohibition of certain substances is largely based on speculation.[160]

To the tattooing industry, some of the most controversial REACH bans pertain to Pigment Blue 15:3 and Pigment Green 7.[161] These two pigments "are among the only, and thus most widely used, blue and green pigments [included] in tattoo inks."[162] Presently, there are no alternatives to these pigments, which comprise approximately "[sixty-five to seventy percent] of the palette that a tattoo artist uses."[163]

One study suggests that Pigment Blue 15:3 and Pigment Green 7 have relatively low toxicity levels in tattoo ink.[164] This research warns that banning these pigments from tattoo ink could lead to the use of riskier, "less-investigated" coloring agent replacements, which consequently puts consumers at risk.[165] Importantly, however, the research also acknowledges that without more data, providing a reliable risk assessment is impossible.[166]

159. *See* Shannon McDonagh, *How the New EU Ink Ban May Be Permanently Scarring the Tattoo Industry*, EURO NEWS (Jan. 5, 2022, 4:53 PM), https://www.euronews.com/culture/2022/01/05/how-the-new-eu-ink-ban-may-be-permanently-scarring-the-tattoo-industry; Steven Brennan, *Tattoo Artists Union and Auville Challenge EU REACH Restriction*, FORESIGHT (Aug. 28, 2024), https://www.useforesight.io/news/tattoo-artists-union-and-auville-challenge-eu-reach-restriction.

160. *See* Brennan, *supra* note 159.

161. Nell Greenfieldboyce, *What's in Tattoo Ink? Why Scientists Want to Know*, NPR (Feb. 13, 2021, 5:00 AM), https://www.npr.org/sections/health-shots/2021/02/13/965549858/as-scientists-study-tattoo-ink-safety-europe-bans-two-widely-used-pigments.

162. Ariana Remmel, *Tattoo Industry Faces an Ink Makeover*, CHEM. & ENG'G NEWS (Dec. 2, 2022), https://cen.acs.org/analytical-chemistry/Tattoo-industry-faces-ink-makeover/100/i43.

163. Greenfieldboyce, *supra* note 161; Priyanka Shankar, *Future Looking Less Bright for EU Tattoo Artists*, DEUTSCHE WELLE (Jan. 7, 2022), https://www.dw.com/en/new-eu-ink-rules-force-tattoo-artists-to-change-their-spots/a-60356164 ("There is no alternative for blue and green pigments.").

164. *See* Remmel, *supra* note 162.

165. *Id.*

166. *Id.*

IV. WE HAVE BEEN HERE BEFORE: REFORMING THE EPA'S CHEMICAL REGULATIONS FRAMEWORK BY WAY OF AN AMENDMENT TO THE TOXIC SUBSTANCES CONTROL ACT

In revamping the cosmetics framework, moving to a more proactive approach is imperative to protect and empower consumers. In addition to looking at the EU's approach, another way to guide our path forward is by looking at how the U.S. has overhauled a similar regulatory scheme in the past, specifically through amendment of the Toxic Substances Control Act ("TSCA").

A. Comparing the Pre-Amended TSCA to the Current Cosmetics Framework

The TSCA gives the Environmental Protection Agency ("EPA") the authority to ensure the safety of chemicals in products on the U.S. market;[167] however, many perceived the TSCA as a failure.[168] Like the present cosmetic regulatory framework, the pre-amended TSCA provided the EPA with limited authority to regulate chemicals already on the market or new chemicals entering the market.[169]

Under the TSCA, the EPA had to approve any new chemical before it entered the market.[170] However, the law exempted over 60,000 chemicals already in use before the TSCA was enacted in 1976.[171] In addition, the only data the EPA could review to determine chemical safety was the data the manufacturers *chose* to share with the EPA.[172] In comparison, under the cosmetics framework, manufacturers must substantiate product safety before marketing, but with a vague safety substantiation standard, cosmetics manufacturers can *choose* their testing methods and data sources.[173]

Moreover, the FDA has the burden of showing an ingredient is harmful "when used as intended," but it cannot require manufacturers to

167. *See* Cory Gerlach, *New Toxic Substances Control Act: An End to the Wild West for Chemical Safety?*, HARV. UNIV.: SCI. NEWS (Oct. 25, 2016), https://sites.harvard.edu/sitn/2016/10/25/new-toxic-substances-control-act-end-wild-west-chemical-safety/. The EPA cannot regulate the chemicals in cosmetics, food, or drugs as those are subject to the jurisdiction of the FDA. *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, H.R. 2576, 114th Cong. (2016) (enacted) ("For purposes of TSCA, the term 'chemicals' does not include food, drugs and cosmetics.").

168. *See* Gerlach, *supra* note 167.

169. *See id.*

170. *Id.*

171. *See id.*

172. *Id.; see* Le, *supra* note 110, at 417–18.

173. *See Product Testing of Cosmetics*, *supra* note 123.

share ingredient safety data.[174] Similarly, the EPA lacked direct access to safety data held by manufacturers and faced the challenge of first demonstrating potential harm from a chemical before it could require testing to assess whether it posed an "unreasonable risk."[175]

B. The Frank R. Lautenberg Chemical Safety for the 21st Century Act

To address the TSCA's major flaws, in 2016, Congress and industry leaders worked together to pass the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Lautenberg Act"). [176] Unlike what MoCRA did for the FDA, the Lautenberg Act significantly bolstered the EPA's authority to regulate chemicals.[177] This legislation introduced a compulsory framework for the EPA to evaluate chemicals currently in use, including the greater than 60,000 chemicals previously exempted from testing under the original law, and required that assessments be completed by judicially enforceable deadlines.[178] Importantly, the EPA must determine the safety of new chemicals before market entry.[179]

The Lautenberg Act also marks the EPA's transition to a risk-based assessment strategy, whereas before, the EPA used a cost-benefit analysis.[180] Thus, a greater emphasis is now placed on a chemical's hazard risk rather than the economic impacts of regulating that chemical,[181] and priority is given to assessing persistent, carcinogenic, or highly toxic chemicals.[182]

The Lautenberg Act greatly improves the transparency of chemical information by restricting companies from claiming confidentiality over relevant data, allowing both consumers and the EPA to gain a clearer understanding of chemical safety.[183] And finally, the Lautenberg Act

174. *See* Le, *supra* note 110, at 418.

175. *Id.*; *see* Gerlach, *supra* note 167.

176. See Richard Denison, *Why Passage of the Lautenberg Act is a Really Big Deal*, ENV'T DEF. FUND (June 10, 2016), https://blogs.edf.org/health/2016/06/10/why-passage-of-the-lautenberg-act-is-a-really-big-deal/; Frank R. Lautenberg Chemical Safety for the 21st Century Act, H.R. 2576, 114th Cong. (2016) (enacted).

177. *See generally* Denison, *supra* note 176.

178. *See id.*; Mark Scialla, *It Could Take Centuries for EPA to Test All the Unregulated Chemicals Under a New Landmark Bill*, PBS NEWS (June 22, 2016, 11:58 AM), https://www.pbs.org/newshour/science/it-could-take-centuries-for-epa-to-test-all-the-unregulated-chemicals-under-a-new-landmark-bill.

179. Denison, *supra* note 176.

180. *See* H.R. 2576; RICHARD A. DENISON, ENV'T DEF. FUND, A PRIMER ON THE NEW TOXIC SUBSTANCES CONTROL ACT (TSCA) AND WHAT LED TO IT, ENVIRONMENTAL DEFENSE FUND 3–5 (2017).

181. *See generally* DENISON, *supra* note 180.

182. Denison, *supra* note 176.

183. *See id.*; DENISON, *supra* note 180, at 7, 12–13.

provides consistent funding to the EPA to carry out these new powers, allowing for a more stable and predictable regulatory process.[184]

V. RECOMMENDATIONS FOR RESTRUCTURING THE COSMETICS REGULATORY FRAMEWORK

Considering the increasing popularity of tattoos, the safety concerns associated with commercial tattoo inks, and the inadequacies of the present cosmetics regulatory framework, a change must be made to how the U.S. regulates tattoo ink.

A. Enhanced Authority for Premarket Reviews

To ensure the safety of cosmetic products like tattoo ink, Congress should grant the FDA premarket authority similar to that of the EPA under the Lautenberg Act.[185] This would involve instituting a mandatory and comprehensive safety assessment for all new cosmetic ingredients before market entry. By doing so, the FDA could proactively protect consumers.

B. Mandatory Assessment of Ingredients Already on the Market

An important lesson from the original TSCA and the Lautenberg Act is how to handle chemicals already on the market.[186] The Lautenberg Act presents the EPA with the necessary but daunting task of going back to assess over 60,000 previously-exempted chemicals.[187] With that in mind, the FDA should be required to conduct regular and systematic reviews of all chemicals currently used in cosmetic products. Strict deadlines should bind this process to ensure the timely evaluation of chemicals and maintain the ongoing assurance of consumer safety.

C. Prioritizing High-Risk Cosmetics and Ingredients

Congress should mandate the FDA to prioritize the assessment and regulation of cosmetic products and ingredients that present higher

184. *See The Frank R. Lautenberg Chemical Safety for the 21st Century Act*, U.S. ENV'T PROT. AGENCY, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act (June 23, 2025).

185. H.R. 2576.

186. *Id.*

187. *See* Scialla, *supra* note 178 ("The EPA will review a minimum of [twenty] chemicals at a time, and each has a seven-year deadline. Industry may then have five years to comply after a new rule is made. At that pace it could take centuries for the agency to finish its review.").

risks. Priority should be given to those ingredients with evidence of persistence, carcinogenicity, or significant toxicity. As there are over 10,000 known ingredients in cosmetic products,[188] prioritization would improve efficiency by streamlining resources and efforts toward mitigating the most serious threats to consumer health.[189]

D. Labeling

The FDA should mandate that manufacturers include warning labels on cosmetic products containing potentially hazardous ingredients. The FDA should also ensure ingredient accuracy across different brands for products like tattoo ink, which are often mislabeled. This could be achieved through random testing of tattoo inks available on the market. When the FDA identifies a mislabeled product, it should use its authority under the FDCA and FPLA to hold manufacturers accountable for violations.

E. Consistent Funding

Finally, Congress should provide consistent and reliable funding to support the FDA so that it may successfully manage its responsibilities of ensuring the safety of cosmetics. A stable financial base would empower the FDA to execute its regulatory duties effectively and predictably.

VI. CONCLUSION

As the popularity of tattoos rises in the United States, our regulations must evolve to reflect the significance and permanence they represent. The risk posed by the ingredients in tattoo inks, in conjunction with a significant number of contaminated and mislabeled inks on the market, begs the question of how tattoo inks are regulated. The inadequacies of the FDA's powers to regulate cosmetics are revealed in addressing this question.

Without adequate safety substantiation standards and premarket review, consumers are left vulnerable to unverified and potentially toxic ink ingredients and contaminants. However, successful reform is possible, as exemplified by other proactive regulatory frameworks. Ultimately, we should reshape the cosmetics regulatory system to

188. *Personal Care Products: What's at Stake?*, SAFER STATES, https://www.saferstates.org/priorities/personal-care-products (last visited May 1, 2025).

189. *See id.*

empower the FDA with the necessary premarket authority to independently assess ingredient safety, mandate the review of existing chemicals, prioritize the evaluation of high-risk cosmetics and ingredients, improve product labeling, and secure consistent funding to support these enhanced regulatory efforts.