NOTE

Amending the Food, Drug, and Cosmetic Act's Labeling Requirements for Cosmetics

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ABSTRACT

The Food, Drug, and Cosmetic Act, enacted in 1938, gives the Food and Drug Administration the power to regulate the cosmetics industry. Congress has enacted numerous laws regarding food, drug, and tobacco products but has not done the same for cosmetic products. It has become more apparent that the chemicals in cosmetics can create or contribute to health issues in product users. Ingredients such as parabens can cause hormone disruptions, while talc can contain asbestos, which was recently found in a cosmetic created for teenagers. In response to public backlash and consumer inquiries, companies have begun to market "clean" beauty products. It remains unclear to product purchasers, however, what "clean" beauty labels truly mean. While members of Congress have introduced bills to regulate the cosmetics industry, the bills have not made it past the committee stage. This Note proposes an amendment to the Food, Drug, and Cosmetic Act that focuses on familiar labeling requirements that will inform consumers of the contents of their cosmetic products. This amendment would require the FDA to implement warning labels for the general population and vulnerable groups while also defining "clean," "natural," and similar packaging claims. This amendment will provide consumers with the ability to make to make informed choices about their cosmetic purchases.

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INTRODUCTION

In 2018, a jury awarded $4.7 billion in damages to twenty-two women in a case against Johnson & Johnson.[1] These women suffered from ovarian cancer after decades-long use of Johnson & Johnson baby powder, which contained talcum powder.[2] Johnson & Johnson's internal memos dating back to the 1970s showed its fear that the talc used in their baby powder was contaminated with asbestos, but the company did not warn consumers about these concerns.[3]

In 2019, the U.S. Food and Drug Administration ("FDA") discovered that Claire's, a brand and chain of stores designed for teenage girls, sold cosmetics that contained asbestos.[4] Claire's initially refused to recall these products, which included eye shadow, contour palettes, and compact powders.[5] The FDA, the agency in charge of cosmetics regulation, lacked statutory authority to recall these products despite the presence of asbestos.[6]

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1 Philippa Roxby, *Johnson & Johnson to Pay $4.7bn Damages in Talc Cancer Case*, BBC (July 13, 2018), https://www.bbc.com/news/business-44816805 [https://perma.cc/P2NL-96HK].

2 *Id.*

3 Roni Caryn Rabin & Tiffany Hsu, *Johnson & Johnson Feared Baby Powder's Possible Asbestos Link for Years*, N.Y. TIMES (Dec. 14, 2018), https://www.nytimes.com/2018/12/14/business/baby-powder-asbestos-johnson-johnson.html[https://perma.cc/F53Y-SFQB].

4 Tiffany Hsu, *F.D.A. Confirms Asbestos in Claire's Products and Calls for Stronger Regulation*, N.Y. TIMES (Mar. 5, 2019), https://www.nytimes.com/2019/03/05/business/claires-cosmetics-asbestos-fda.html [https://perma.cc/B97P-Z2Q3].

5 *Id.*

6 *Id.*

This issue drew more attention to the outdated regulatory scheme for cosmetics that does very little to inform consumers about the harmful chemicals that may lurk in the products they purchase.[7] In recent years, consumers have increasingly demanded cleaner products and greater transparency, leading to the rise of the "clean beauty" industry.[8] Consumers may be unaware, however, that the FDA does not regulate terms such as "clean" and "natural."[9] Thus, while consumers may believe that they are making healthy choices in response to recently revealed issues in the cosmetics industry, they may be misguided by large companies.[10] Increased FDA regulation of the cosmetics industry can solve this issue.

In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), the first law to give the FDA its authority to regulate the cosmetics industry.[11] Over eighty years later, very few amendments to the FD&C Act have changed the regulatory scheme for cosmetics, in contrast to the numerous amendments that have updated practices for food and drug regulation[12] as well as the far more protective regulations present in other countries.[13] Research has revealed the harmful nature of chemicals that are used in cosmetics, which include carcinogens and endocrine disruptors that can cause cancer, reproductive issues, congenital disorders, and other long-

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7 *Id.*

8 Dina ElBoghdady, *'Clean' Beauty Has Taken Over the Cosmetics Industry, but That's About All Anyone Agrees On*, WASH. POST (Mar. 11, 2020), https://www.washingtonpost.com/lifestyle/wellness/clean-beauty-has-taken-over-the-cosmetics-industry-but-thats-about-all-anyone-agrees-on/2020/03/09/2ecfe10e-59b3-11ea-ab68-101ecfec2532_story.html [https://perma.cc/ZV4R-7NVB].

9 *Id.*

10 *See id.*; Carla Burns, *'Natural' or 'Organic' Cosmetics? Don't Trust Marketing Claims.*, ENV'T WORKING GRP., (Jan. 11, 2018), https://www.ewg.org/news-and-analysis/2018/01/natural-or-organic-cosmetics-don-t-trust-marketing-claims [https://perma.cc/7JTQ-72L9].

11 *Milestones in U.S. Food and Drug Law History*, FDA (Jan. 31, 2018), https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/milestones-us-food-and-drug-law-history [https://perma.cc/CYP5-3U8T].

12 *See Selected Amendments to the FD&C Act*, FDA (Mar. 29, 2018), https://www.fda.gov/regulatory-information/laws-enforced-fda/selected-amendments-fdc-act [https://perma.cc/NW8D-3UDC].

13 *International Laws*, CAMPAIGN FOR SAFE COSMETICS, https://www.safecosmetics.org/get-the-facts/regulations/international-laws/ [https://perma.cc/DY9T-9ZX5].

term health issues.[14] In the last few years, some activist groups and legislators have pushed for increased regulation of the cosmetics industry.[15]

It is time for Congress to update the FD&C Act to provide the FDA with additional authority and guidance regarding cosmetics regulation. This would empower the FDA to fill the gap that currently exists in the regulatory framework, particularly with labeling. The FD&C Act's regulation of cosmetics is not nearly as robust as it is for other FDA-regulated products.[16] While Congress has forced the FDA to impose labeling requirements on food, drug, and tobacco manufacturers that serve to increase consumer knowledge,[17] it has very rarely done the same for cosmetics.[18] Members of Congress have proposed bills to increase regulation of the cosmetics industry, but these bills failed to reach a vote.[19] A focus on implementing familiar warning label requirements and standards for product claims that are similar to those already implemented by the FDA for other products would provide a strong starting point for changing the regulatory scheme for cosmetics. These changes will increase consumer awareness of the issues with cosmetics, opening the door for increased regulation in the coming years as demanded by consumers.

Part I of this Note discusses the toxic chemicals used in cosmetics and their potential to have harmful health effects on product users. Part II discusses the current state of the law in cosmetics regulation, including the FDA's regulatory system for cosmetics, notable omissions from regulations, and past legislative proposals. Then, Part III discusses current labeling requirements and standardization imposed by the government for food, drugs, tobacco, and alcohol. Finally, this Note outlines a proposal to amend the FD&C Act to increase labeling requirements. The amendment would require the FDA to: 1) order warning labels for the general population and vulnerable groups, such as pregnant women and children, and 2) standardize terms such as "natural" and "clean" that have been recently added to more and more cosmetic labels.

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14 Scott Faber, *The Toxic Twelve Chemicals and Contaminants in Cosmetics*, ENV'T WORKING GRP. (May 5, 2020), https://www.ewg.org/californiacosmetics/toxic12/ [https://perma.cc/7HX3-SFVR].

15 *See, e.g.*, Scott Faber, *Real Reform Needed for Outdated Cosmetics Laws*, ENV'T WORKING GRP. (Dec. 8, 2016), https://www.ewg.org/enviroblog/2016/12/real-reform-needed-outdated-cosmetics-laws [https://perma.cc/99KC-PKN3].

16 *See infra* Part III.

17 *See id.*

18 *See* CONG. RSCH. SERV., R42594, FDA REGULATION OF COSMETICS AND PERSONAL CARE PRODUCTS 19 (2012).

19 *See* Personal Care Products Safety Act, S. 2100, 117th Cong. (2021); Cosmetic Safety Enhancement Act of 2019, H.R. 5279, 116th Cong. (2019).

I. THE HARMFUL EFFECTS OF CHEMICALS IN COSMETICS

Everyday cosmetic and personal care products, such as shampoo, makeup, toothpaste, and deodorant, can contain harmful chemicals, including carcinogens and endocrine disruptors.[20] Carcinogens are defined as "a substance or agent causing cancer."[21] Endocrine disruptors are "chemicals that mimic, block, or interfere with hormones in the body's endocrine system."[22] Endocrine disruptors may increase or decrease the production of some hormones, imitate or convert certain hormones into others, result in premature cell death, and have other harmful effects.[23] Chemicals in cosmetics can also serve as allergens[24] or cause reproductive issues.[25] While there are numerous toxic chemicals present in such products,[26] a discussion of three key chemicals illustrates the severity and widespread nature of the problem.

Formaldehyde is a known human carcinogen used in cosmetic products.[27] Formaldehyde can be found in some nail polish, nail hardeners, liquid hand soap, and skin moisturizers.[28] Though formaldehyde itself is not used in cosmetics as much as it was previously, formaldehyde releasers are still used.[29] These are preservatives that release formaldehyde through

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20 *Cosmetics*, AM. CANCER SOC'Y (May 28, 2014), https://www.cancer.org/cancer/cancer-causes/cosmetics.html [https://perma.cc/3UNP-BDKC].

21 Carcinogen, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/carcinogen [https://perma.cc/9RQP-2SBF].

22 *Endocrine-Disrupting Chemicals*, ENDOCRINE SOC'Y, https://www.endocrine.org/topics/edc [https://perma.cc/E95G-JE8J].

23 *Dirty Dozen Endocrine Disruptors*, ENV'T WORKING GRP. (Oct. 28, 2013), https://www.ewg.org/research/dirty-dozen-list-endocrine-disruptors [https://perma.cc/BY2T-CBSA].

24 *See Allergens in Cosmetics*, FDA (Feb. 10, 2022), https://www.fda.gov/cosmetics/cosmetic-ingredients/allergens-cosmetics [https://perma.cc/T5LK-FQRW].

25 *See* Faber, *supra* note 14.

26 *See id.*

27 *The Dirty Dozen: Formaldehyde-Releasing Preservatives*, DAVID SUZUKI FOUND., https://davidsuzuki.org/queen-of-green/dirty-dozen-formaldehyde-releasing-preservatives/ [https://perma.cc/UNL9-X8GT].

28 *Id.*; *Formaldehyde in Cosmetic Products*, PROD. SAFETY AUSTRALIA, https://www.productsafety.gov.au/products/health-lifestyle/cosmetics/formaldehyde-in-cosmetic-products [https://perma.cc/2ANS-G45F]; *Formaldehyde and Formaldehyde-Releasing Preservatives*, CAMPAIGN FOR SAFE COSMETICS, https://www.safecosmetics.org/get-the-facts/chemicals-of-concern/formaldehyde/ [https://perma.cc/U33X-LLWF].

29 *See* Laura Malinauskiene, *Formaldehyde May Be Found in Cosmetic Products Even When Unlabelled*, 10 OPEN MED. 323, 323 (2015); Jessica Burman, *Is There Formaldehyde*

chemical reactions, particularly with exposure to water, as with shampoos and conditioners.[30] High exposure to formaldehyde from cosmetic products can cause skin sensitization, breathing issues, and asthma, while chronic high exposure can cause cancer.[31] In the European Union, if a product contains a concentration of 0.05% formaldehyde, the product must have a label stating that it "contains formaldehyde."[32]

Parabens are known endocrine disruptors.[33] They have been widely used in cosmetics—in particular, shampoos, conditioners, moisturizers, deodorants, and toothpastes.[34] When included in cosmetics, parabens are absorbed through the skin.[35] Urine tests show a significantly higher level of certain long-chain parabens present in women, likely reflecting their heavier use of cosmetic products.[36] As endocrine disruptors, parabens can cause reproductive issues in both men and women, change birth outcomes, increase the risk of cancer, and irritate users' skin.[37]

Another key cosmetic ingredient of concern is talc.[38] An FDA study found that 20% of tested cosmetics that included talc also contained asbestos, a carcinogen.[39] Talc may be found in deodorant, baby powder, lotion, eyeshadow, lipstick, and more.[40] There is a link between talcum powder and cancer, and ovarian cancer in particular, due to the potential for asbestos

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in Your Shampoo?, ALTS J. (May 15, 2013), https://www.alternativesjournal.ca/blog/is-there-formaldehyde-in-your-shampoo/ [https://perma.cc/L4DB-TK6R].

30 *Id.*; Johanna Congleton, *Chemicals That Should Disappear from Cosmetics*, ENV'T WORKING GRP. (Jan. 6, 2014), https://www.ewg.org/enviroblog/2014/01/chemicals-should-disappear-cosmetics [https://perma.cc/P5AW-9X9B].

31 *Formaldehyde in Cosmetic Products*, *supra* note 28.

32 Laura Malinauskiene, Audra Blaziene, Anzelika Chomiciene, & Marléne Isaksson, *Formaldehyde May Be Found in Cosmetics Products Even When Unlabelled*, 323 Open Med. 323 (2015).

33 Tasha Stoiber, *What Are Parabens, and Why Don't They Belong in Cosmetics?*, ENV'T WORKING GRP. (Apr. 9, 2019),
https://www.ewg.org/californiacosmetics/parabens [https://perma.cc/Q47R-B5MH].

34 *Id.*

35 *Parabens*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Apr. 7, 2017), https://www.cdc.gov/biomonitoring/Parabens_FactSheet.html [https://perma.cc/U5UT-6MQV].

36 *Id.*

37 Stoiber, *supra* note 33.

38 *Talc*, CAMPAIGN FOR SAFE COSMETICS, http://www.safecosmetics.org/get-the-facts/chemicals-of-concern/talc/ [https://perma.cc/NDZ9-GUJ9].

39 *FDA Tests Find Asbestos in Nearly 20 Percent of Cosmetics Products*, ENV'T WORKING GRP. (Mar. 9, 2020), https://www.ewg.org/release/fda-tests-find-asbestos-nearly-20-percent-cosmetics-products [https://perma.cc/F3T3-4DJE].

40 *Talc*, *supra* note 38.

exposure.[41] Talcum powder containing asbestos was the subject of several recent cases against Johnson & Johnson involving women who have developed ovarian cancer after long-term use of the company's baby powder, as well as the 2019 Claire's product recall controversy.[42]

Pregnant women and young children are particularly vulnerable to harmful chemicals used in cosmetics.[43] Furthermore, issues regarding chemicals in cosmetics inordinately impact women of color.[44] A recent study showed that women of color "are disproportionately exposed to worrisome chemicals compared to white women" through the personal care products marketed toward them.[45] The Environmental Working Group reported that about one in twelve cosmetic products marketed to Black women fall into their "highly hazardous" category of products.[46]

II. THE GOVERNMENT'S OUTDATED REGULATION OF COSMETICS

A. The Current State of the Law

In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), the law that first gave the FDA the power to regulate certain aspects of the cosmetic industry.[47] The FD&C Act defines the term "cosmetics" as:

> "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleaning, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a

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41 *Talcum Powder and Cancer*, AM. CANCER SOC'Y (Feb. 4, 2020), https://www.cancer.org/cancer/cancer-causes/talcum-powder-and-cancer.html [https://perma.cc/BX84-EECB].

42 *See* Roxby, *supra* note 1; Rabin & Hsu, *supra* note 3; Hsu, *supra* note 4.

43 Cécile Marie, Sophie Cabut, Françoise Vendittelli, & Marie-Pierre Sauvant-Rochat, *Changes in Cosmetics Use During Pregnancy and Risk Perception by Women*, 13 INT'L J. OF ENV'T RSCH. AND PUB. HEALTH 383, 383 (2016); Ami R. Zota & Bhavna Shamasunder, *The Environmental Injustice of Beauty: Framing Chemical Exposures from Beauty Products as a Health Disparities Concern*, 217 AM. J. OBSTETRICS & GYNECOLOGY 418, 418 (2017).

44 Meera Senthilingam, *Could African-American Beauty Products Pose Health Risks?*, CNN (Dec. 8, 2016, 9:14 AM), https://www.cnn.com/2016/12/06/health/african-american-beauty-products-hazardous/index.html [https://perma.cc/HS8W-B7BB].

45 Nneka Leiba & Paul Pestano, *Study: Women of Color Exposed to More Toxic Chemicals in Personal Care Products*, ENV'T WORKING GRP. (Aug. 17, 2017), https://www.ewg.org/enviroblog/2017/08/study-women-color-exposed-more-toxic-chemicals-personal-care-products [https://perma.cc/AL8P-RP27] (citing Zota & Shamasunder, *supra* note 43, at 418).

46 *Big Market for Black Cosmetics, but Less-Hazardous Choices Limited*, ENV'T WORKING GRP. (Dec. 6, 2016), https://www.ewg.org/research/big-market-black-cosmetics-less-hazardous-choices-limited [https://perma.cc/VY6P-KKPM].

47 *Milestones in U.S. Food and Drug Law History*, *supra* note 11.

> component of any such articles; except that such term shall not include soap."[48]

The FD&C Act's definition of cosmetics includes a wide variety of products including makeup, moisturizer, perfume, hair dye, nail polish, deodorant, and nonmedicated shampoos.[49] Some personal care products qualify as both cosmetics and drugs.[50] For example, antidandruff shampoo falls into both categories because it is used for both cleansing and treatment purposes.[51] Products that qualify as both cosmetics and drugs must meet the requirements for both categories.[52] Unlike most drugs, cosmetics are not required to undergo premarket approval processes.[53] Rather, the FDA permits cosmetics companies to make their own determinations as to whether their products are safe.[54] A 2016 poll found that two-thirds of consumers believe that the FDA reviews the chemicals in cosmetics.[55]

Most cosmetic safety determinations are based on the short-term effects of the chemicals within them, yet long-term effects may arise and are widely unstudied.[56] Furthermore, the chemicals used in cosmetics are often tested on an individual basis, failing to consider the effects of certain combinations of chemicals.[57] While the harmful effects of talc and asbestos have been recognized,[58] the potential long-term impacts of other chemicals used in cosmetics have not been widely studied.[59]

The FD&C Act has few labeling requirements for cosmetics relative to other FDA-related products.[60] It "prohibits the distribution of cosmetics which are adulterated or misbranded."[61] A cosmetic is misbranded "if its labeling is false or misleading, if it does not bear the required labeling

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48 21 U.S.C. § 321.

49 *Are All "Personal Care Products" Regulated as Cosmetics?*, FDA (Feb. 1, 2016), https://www.fda.gov/industry/fda-basics-industry/are-all-personal-care-products-regulated-cosmetics [https://perma.cc/8CKD-MDX3].

50 *Id.*

51 *Id.*

52 *Id.*

53 *Id.*

54 *Id.*

55 Faber, *supra* note 14.

56 *See Cosmetics*, *supra* note 20.

57 *See id.*

58 Rabin & Hsu, *supra* note 3.

59 *See Cosmetics*, *supra* note 20.

60 *See Summary of Cosmetics Labeling Requirements*, FDA (Aug. 24, 2020), https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/summary-cosmetics-labeling-requirements [https://perma.cc/8QFF-9QL7].

61 *Id.*

information, or if the container is made or filled in a deceptive manner."[62] The FD&C Act's current packaging label requirements include a list of ingredients and a warning label for cosmetics "which may be hazardous to consumers when *misused,*" but do not specifically require a warning label for cosmetics that may be hazardous when used properly.[63] The FDA is authorized to provide warnings labels for cosmetic products that are potentially unsafe,[64] but cosmetics companies are left to determine the safety of their own products.[65] Thus, chemicals known to be harmful remain in cosmetic products without a warning label indicating their presence.[66]

The FDA has no definitions or standards for terms like "natural," "organic," "nontoxic," "plant-based," "clean," and a plethora of other terms placed prominently on the packaging of many cosmetic products.[67] Only the term "organic" has some standards for cosmetic products: the United States Department of Agriculture ("USDA") enforces rules about which products can be labeled as "organic," depending on the proportion of USDA organic ingredients used in the product.[68] The FDA itself has not designed specific standards for the term "organic" for use on cosmetics packaging.[69] One survey found that 74% of women living with their children and 60% of other women find it important to purchase "green" or "natural" products.[70] Notably, more companies have begun using "clean" claims due to the rise of the "clean beauty" movement and the increasing consumer awareness regarding cosmetics safety.[71] Similarly, more recent concerns about products containing parabens have led to standardless "paraben free" claims on packaging.[72]

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62 *Id.*

63 *Id.* (emphasis added).

64 *See* 21 C.F.R. § 740.1(a) (2021); CONG. RSCH. SERV., *supra* note 18, at 38.

65 *See* CONG. RSCH. SERV., *supra* note 18, at 11.

66 *See id.* at 38.

67 Burns, *supra* note 10.

68 Christina Animashaun, *The "Natural" Beauty Industry Is On the Rise Because We're Scared of Chemicals*, VOX (Sept. 18, 2018, 7:00 AM), https://www.vox.com/the-goods/2018/9/18/17866150/natural-clean-beauty-products-feinstein-cosmetics-bill-fda [https://perma.cc/5PNJ-6FEU].

69 *Id.*

70 Burns, *supra* note 10.

71 Animashaun, *supra* note 68.

72 Kathryn Watson, *What Does Paraben-Free Mean in Beauty Products?*, HEALTHLINE (June 16, 2020), https://www.healthline.com/health/paraben-free [https://perma.cc/2Q8U-DNJA].

B. Attempts to Pass Federal Cosmetics Legislation

Congress has only amended the FD&C Act twice with respect to cosmetics regulation since the bill was enacted in 1938.[73] Throughout the last few years, legislators have attempted to pass federal cosmetics bills, but these bills have not made it past the committee stage of the process.[74] Many of these proposals include more sweeping regulations of the cosmetics system.[75] For example, the proposed Personal Care Products Safety Act and the Cosmetic Safety Enhancement Act included requirements for registration of cosmetics facilities, mandatory recall authority, labeling requirements, animal testing, addressing counterfeit cosmetics, foreign supplier verification, and more.[76] These bills would have required warnings labels for the general population and vulnerable populations like pregnant women and children.[77] The other main labeling requirement would have been a label indicating that some products are for professional use only.[78] However, these acts would still leave the general population vulnerable to claims that products are "clean" or "natural." While the Natural Cosmetics Act would resolve issues with the lack of standardization for the term "natural,"[79] it would leave out other terms that have become more commonly used, including "clean," "green," and "nontoxic."

In a House subcommittee hearing on the Safe Cosmetics and Personal Care Products Act of 2019 and the Cosmetic Safety Enhancement Act of 2019, the primary concerns of hesitant lawmakers regarded effects on state law and the lack of protection for small businesses who benefit from the lack of regulation and ease of entry in the cosmetics industry.[80] At the hearing, a small business owner discussed how small cosmetics companies make safe products and why the proposed regulations would be overburdensome.[81]

On the other hand, very narrow cosmetics bills, such as the Natural Cosmetics Act and the Children's Product Warning Label Act of 2019, failed

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73 CONG. RSCH. SERV., *supra* note 18.

74 Personal Care Products Safety Act, S. 2100, 117th Cong. (2021); Cosmetic Safety Enhancement Act of 2019, H.R. 5279, 116th Cong. (2019).

75 *See* S. 2100; H.R. 5279.

76 S. 2100; H.R. 5279.

77 *See* S. 2100; H.R. 5279.

78 *See* S. 2100; H.R. 5279.

79 *See* Natural Cosmetics Act, H.R. 5872, 117th Cong. (2021).

80 *See Building Consumer Confidence by Employing the FDA to Improve Cosmetic Safety: Hearing Before the Subcomm. on Health of the Comm. on Energy and Com.*, 116th Cong. (2019).

81 *See id.* (statement of Leigh O'Donnell, Executive Director of The Handcrafted Soap and Cosmetic Guild, Inc.).

to gain traction after being referred to the subcommittee.[82] The state of California passed an historic cosmetics law in 2020, the Toxic-Free Cosmetics Act, which banned the use of certain chemicals, like formaldehyde,[83] from use in cosmetics, overcoming pressure from the cosmetics industry that defeated an identical bill in the prior year.[84] Members of the industry claimed that there was a lack of scientific evidence to support banning the listed chemicals, asbestos and lead among them.[85] Further, the California Chamber of Commerce referred to the previous iteration of the bill as a "jobs killer."[86]

III. LABELING AND STANDARDIZATION REQUIREMENTS FOR FOOD, DRUGS, AND OTHER PRODUCTS

Several comparable FDA labeling requirements could serve as a foundation and reference for cosmetics labeling. Food and drug labeling provides consumers with additional information about what comprises their products and how those ingredients might impact their health.[87] Labels on alcohol and tobacco products provide specific warnings to consumers.[88] Additionally, food and tobacco manufacturers are required to abide by standards for the terms used on their labeling, such as "low" or "light."[89]

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82 The Natural Cosmetics Act would require standards for the term "natural," while the Children's Product Warning Label Act of 2019 addressed warning labels for children's cosmetics containing talc that is not free of asbestos. *Compare* H.R. 5872, *with* Children's Product Warning Label Act of 2019, H.R.1816, 116th Cong. (2019).

83 *Governor Newsom Signs Legislation Making California First in the Nation to Ban Toxic Chemicals in Cosmetics*, OFF. GOVERNOR GAVIN NEWSOM (Sept. 30, 2020), https://www.gov.ca.gov/2020/09/30/governor-newsom-signs-legislation-making-california-first-in-the-nation-to-ban-toxic-chemicals-in-cosmetics/ [https://perma.cc/PST2-EY2X]; *California First State to Ban 24 Toxic Chemicals in Personal Care Products and Cosmetics*, ENV'T WORKING GRP. (Sept. 30, 2020), https://www.ewg.org/release/california-first-state-ban-24-toxic-chemicals-personal-care-products-and-cosmetics [https://perma.cc/DM7W-L9RQ].

84 David Lazarus, *Cosmetics Industry Crushes Bill That Would Have Made Makeup and Hair Products Safer*, L.A. TIMES (Apr. 10, 2019, 5:00 AM), https://www.latimes.com/business/lazarus/la-fi-lazarus-california-cosmetics-regulation-20190410-story.html [https://perma.cc/Q3UT-SHHC].

85 *Id.*

86 *Id.*

87 *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990); 21 CFR § 201.63.

88 *See* 27 U.S.C. § 215(a); *Labeling and Warning Statements for Tobacco Products*, FDA (Jan. 14, 2021), https://www.fda.gov/tobacco-products/products-guidance-regulations/labeling-and-warning-statements-tobacco-products [https://perma.cc/YYK4-A5T9].

89 *See The Nutrition Labeling and Education Act of 1990*, BARNARD HEALTH CARE (Sept. 4, 2020), https://www.barnardhealth.us/food-processing/the-nutrition-labeling-and-education-act-of-1990.html [https://perma.cc/46LD-288E]; *Use of "Light," "Mild," "Low,"*

Elements of these labeling structures could be used as a basis for improved cosmetics labeling.

A. The Ample Information and Warnings Available to Consumers on Other Product Labels

Labels for food, drugs, and tobacco contain much more than just an ingredient list, providing consumers with a comprehensive understanding of the health risks posed by their products. Beginning in the 1960s, consumers became more concerned with the contents of their food and how it would impact their health.[90] The government soon became aware that food companies were making false claims on their packaging.[91] In 1990, Congress passed the Nutrition Labeling and Education Act ("NLEA") to amend the FD&C Act, which gave the FDA the authority to require nutrition labels with specific detail; this change created many of the food labeling standards used today.[92] The law required companies to list important information including serving size, number of calories, sugar content, and other now-familiar categories.[93]

Drug labeling has also been updated in recent decades to provide pertinent health information to consumers.[94] In 1970, the FDA implemented the first regulation to require medication be accompanied by patient package inserts—leaflets describing instructions, side effects, and other key information about the medication.[95] After a series of hearings, as well as a survey that revealed that women were not receiving adequate information about the risks of oral contraceptives from their doctors,[96] the FDA required an informational insert with each package of oral contraceptives.[97] The Senate hearings on this issue and media coverage of the hearings promoted

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or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products, FDA (June 2010), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-light-mild-low-or-similar-descriptors-label-labeling-or-advertising-tobacco-products [https://perma.cc/3J63-NXLJ].

90 INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PHASE I REPORT 19 (Ellen A. Wartella et al. eds., 2010).

91 *Factual Food Labels: A Closer Look at the History*, UNIV. TEX. AUSTIN DEP'T NUTRITIONAL SCIS. (Apr. 6, 2018), https://he.utexas.edu/ntr-news-list/food-labels-history [https://perma.cc/88RJ-V9PP].

92 Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

93 *Id.*

94 *See* Elizabeth Siegal Watkins, *Expanding Consumer Information: The Origin of the Patient Packet Insert*, 10 ADVANCING CONSUMER INT. 20, 20 (1998).

95 *Id.* at 24.

96 *Id.* at 22.

97 *Id.* at 24.

a great deal of public awareness,[98] which led to increased advocacy for a package insert and backlash against an attempt to shorten the proposed insert.[99] The FDA changed the requirements in 1977 to provide even more information to consumers.[100]

Further, for over-the-counter drugs, the FDA implemented a simple pregnancy and breastfeeding warning.[101] This warning says, "If pregnant or breast-feeding, ask a health professional before use."[102] This type of label provides a straightforward way to let a consumer know when a medication might pose a reproductive risk to them or their child. Sunscreen, a product regulated as an over-the-counter drug due to its preventative medical purpose, requires particular warning labels.[103] For example, sunscreens within a certain SPF range must include a "Skin Cancer/Skin Aging Alert" that warns consumers that the product "has been shown only to help prevent sunburn, not . . . skin cancer or early skin aging."[104]

The FDA also imposes strict labeling rules for tobacco products, requiring warning statements on packaging.[105] The FDA first implemented cigarette labeling requirements in 1966 after Congress passed the Federal Cigarette Labeling and Advertising Act.[106] Congress directed the FDA to implement further changes in 2009 through an FD&C Act amendment that required warning labels for smokeless tobacco products.[107] It also required tobacco companies to disclose information about their ingredients and allowed the FDA to regulate the quantities of harmful ingredients in tobacco products.[108]

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98 *Id.* at 21.

99 *Id.* at 23.

100 *Id.* at 25.

101 *See* 21 CFR § 201.63 (2021). Specifically, this warning is required for "drug products that are intended for systemic absorption." *Id.*

102 *Id.*

103 *See* 21 CFR § 201.327 (2021).

104 *Id.*

105 *See Labeling and Warning Statements for Tobacco Products*, *supra* note 88.

106 *See FDA Proposes New Health Warnings for Cigarette Packs and Ads*, FDA (May 1, 2020), https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/fda-proposes-new-health-warnings-cigarette-packs-and-ads [https://perma.cc/UD5A-SSTC]; *Smoking & Tobacco Use*, CDC WEB ARCHIVE (July 21, 2015), https://www.cdc.gov/tobacco/data_statistics/sgr/2000/highlights/labels/index.htm [https://perma.cc/6WYH-9ND3].

107 *See FDA Proposes New Health Warnings for Cigarette Packs and Ads*, *supra* note 106.

108 *Family Smoking Prevention and Tobacco Control Act – An Overview*, FDA (June 3, 2020), https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview [https://perma.cc/77CK-68QF].

In 1984, Congress enacted the Comprehensive Smoking Education Act, requiring causal health warnings for pregnancy, lung cancer, heart disease, and more.[109] Research has demonstrated that warning labels with strong causal statements are more effective than those without them, as they most discourage purchase of the product at hand.[110] The FDA uses this type of labeling with cigarettes and tobacco products.[111] Health warnings on tobacco packaging have aided consumers in understanding the risks that such products pose.[112] In 2019, the FDA also proposed warning labels for cigarettes that require more causal language, accompanied with photos illustrating the potential effects of the product.[113] Health warnings labels with strong causal language have been found to be more effective for not just cigarettes, but also sugary beverages and alcohol.[114] Medical professionals have encouraged the increased use of such language for warning labels for sodas as well.[115] A California poll found that 78% of those surveyed would favor warning labels on sugary drinks.[116]

The federal government has also mandated warning labels on alcohol by statute.[117] One particular labeling requirement is designed for pregnant women, stating, "According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects."[118] The implementation of the label created greater awareness of

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109 *Smoking & Tobacco Use*, *supra* note 106. An example of one such specific health warning is as follows: "SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight." *Id.*

110 Marissa G. Hall, Anna H. Grummon, Olivia M. Maynard, Madeline R. Kameny, Desmond Jenson, & Barry M. Popkin, *Causal Language in Health Warning Labels and US Adults' Perception: A Randomized Experiment*, 109 AM. J. PUB. HEALTH 1429 (Oct. 1, 2019). Causal language refers to statements that a product "causes" a particular result. *Id.*

111 *See* Lucy Popova, *Sugar-Sweetened Beverage Warning Labels: Lessons Learned from the Tobacco Industry*, 44 J. CAL. DENTAL ASS'N 633, 633 (2016).

112 D. Hammond, G. T. Fong, A. McNeill, R. Borland, & K. M. Cummings, *Effectiveness of Cigarette Warning Labels in Informing Smokers About the Risks of Smoking: Findings from the International Tobacco Control (ITC) Four Country Survey*, 15 (Suppl 3) TOBACCO CONTROL iii15, iii23 (June 2006).

113 *Cigarette Health Warnings*, FDA (Jan. 30, 2020), https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-health-warnings. One of the thirteen proposed health warnings is as follows: "WARNING: Smoking during pregnancy stunts fetal growth." [https://perma.cc/6JCZ-S8Q4].

114 *See* Hall et al., *supra* note 110.

115 *See* Popova, *supra* note 111.

116 *Warning Labels*, HEALTHY FOOD AM., https://www.healthyfoodamerica.org/warninglabels [https://perma.cc/3K7E-PVE8].

117 *See* 27 U.S.C. § 215(a).

118 *Id.*

such risks.[119] It has been effective in preventing drinking during pregnancy among light-drinking women and providing awareness of the risks of drinking during pregnancy to women who drank more heavily.[120]

Studies have generally shown warning labels to be effective in garnering the attention of consumers,[121] which allows consumers to make informed choices about their purchases. That is particularly true where the causal language is implemented for tobacco products.[122]

B. The Standardization of Terms for Food and Tobacco Labels

In 1990, Congress passed the Nutrition Labeling and Education Act.[123] In addition to the aforementioned labeling requirements and nutrition panel, this law also required the FDA to define and standardize the use of vague descriptive terms on food packaging such as "light" and "low fat."[124] Companies manufacturing food products must also comply with very specific requirements in order to make "free from" claims on their labels.[125] For example, to claim that a product is "sugar free," the company's product must contain less than 0.5 grams of sugar per the amount typically consumed or the amount per serving.[126] The FDA has provided similar restrictions for food packaging labeled "sodium free" and "cholesterol free," among other labels.[127]

In addition to these general FDA regulations on food labeling, the USDA implements standards for labeling eggs, meat, and poultry.[128] The USDA first implemented labeling requirements for the food it regulates after demand for more product information increased.[129] Food labels under USDA jurisdiction can only make nutrition claims when the term used on the

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119 Janet R. Hankin, Ira J. Firestone, James L. Sloan, Joel W. Ager, Allen C. Goodman, Robert J. Sokol, & Susan S. Martier, *The Impact of the Alcohol Warning Label on Drinking During Pregnancy*, 12 J. PUB. POL'Y & MKTG. 10, 16–17 (1993).

120 *Id.* at 11, 16–17.

121 Jennifer J. Argo & Kelley J. Main, *Do Warning Labels Really Work?*, ASS'N CONSUMER RSCH. (2004), https://www.acrwebsite.org/web/acr-content/705/do-warning-labels-really-work.aspx [https://perma.cc/5VG4-8FJZ].

122 *See* Hall et al., *supra* note 110.

123 Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

124 *See id.* at § 3(a).

125 *See* 21 CFR §§ 101.54–101.69 (2021).

126 *See* 21 CFR § 101.60 (2021).

127 *See* 21 CFR §§ 101.61–101.62 (2021).

128 *See* U.S. DEP'T OF AGRICULTURE, A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS (Aug. 2007), https://www.fsis.usda.gov/guidelines/2007-0001.

129 *Factual Food Labels: A Closer Look at the History*, *supra* note 91.

packaging has been defined and the product meets that definition.[130] These label regulations include the use of terms such as "low," "modified," "sodium free," "healthy," and other definitions similar to those used by the FDA for other food packaging.[131]

The standardization of health terms on labels has also been used to regulate the tobacco industry.[132] Packaging on tobacco products might state a particular risk level to provide consumers with awareness as to how much the product may impact their health.[133] The FDA regulates the use of terms such as "light," "mild," and "low" for product risk levels on tobacco packaging.[134] This change was made as a result of the Family Smoking Prevention and Tobacco Control Act in 2009, which amended the FD&C Act.[135] The need for that legislation arose because some consumers who may have considered quitting smoking shifted from their typical cigarette purchases to those labeled "light," "mild," or "low" risk, and the FDA wanted to set a "high bar" for these claims due to their influence on consumer behavior.[136]

IV. THE NEED FOR STRICTER COSMETICS LABELING REQUIREMENTS

Consumers should know about the health hazards that unsuspecting cosmetic products can pose to them, just as they know how certain food, drug, and tobacco products can cause them harm or contribute to existing health issues.[137] This lack of information is particularly concerning when considering that on average, women are exposed to 168 chemical ingredients and men are exposed to eighty-five chemical ingredients each day through the use of personal care products.[138] This Note argues that legislation focused on increasing labeling requirements will serve as an important method of increasing consumer awareness and bringing cosmetics regulation in line with the FDA's regulation of other products.

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130 *See id.* at 73.

131 *Id.* at 75–98.

132 *See Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products*, *supra* note 89.

133 *See id.*

134 *Family Smoking Prevention and Tobacco Control Act – An Overview*, *supra* note 108.

135 *Id.*

136 *FDA Authorizes Modified Risk Tobacco Products*, FDA (May 4, 2020), https://www.fda.gov/tobacco-products/advertising-and-promotion/fda-authorizes-modified-risk-tobacco-products [https://perma.cc/4UNC-F3JP].

137 *See supra* Part III.

138 *Personal Care Products Safety Act Would Improve Cosmetics Safety*, ENV'T WORKING GRP., https://www.ewg.org/personal-care-products-safety-act-would-improve-cosmetics-safety [https://perma.cc/4F7V-TVEF].

Purchasers are currently unable to make informed choices about their cosmetics purchases due to the lack of transparency regarding the content of their products. Consumers who attempt to make informed choices by buying products labeled "clean" or "natural" might purchase products that are not as healthy as they would appear because the FDA has provided no definitions or requirements for using these terms.[139] While some argue that research on the long-term effects of chemicals in cosmetics is lacking,[140] it is very difficult to conduct studies that would determine the long-term effects of such chemicals, and thus few such studies have occurred.[141] Yet it is still clear that the harmful effects of chemicals in cosmetic products can present themselves years later. That is illustrated by the lawsuits against Johnson & Johnson by women who used the company's talcum powder and developed ovarian cancer after decades of use.[142] Because of the effects that chemicals in cosmetics can have on consumers' health, other countries such as Canada and members of the European Union have passed legislation far more restrictive on the cosmetics industry than the United States.[143] Congress must take action and direct the FDA to implement more labeling requirements for cosmetics companies to alleviate this issue.

The FDA's regulation of cosmetics, and their labeling requirements specifically, lags far behind that of food, drugs, and tobacco.[144] This gap in regulation is present despite the fact that cosmetics can contain carcinogens, endocrine disruptors, allergens, and other chemicals that pose the potential for reproductive harm or impact particularly vulnerable groups.[145] Despite the health impacts that the chemicals in cosmetics can have,[146] there is a complete lack of regulation for labeling in contrast to what is present for other FDA regulated products.[147]

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139 *See Summary of Cosmetics Labeling Requirements*, *supra* note 60.

140 Lazarus, *supra* note 84.

141 *See Cosmetics*, *supra* note 20.

142 Roxby, *supra* note 1.

143 *See International Laws*, *supra* note 13 and accompanying text.

144 *See supra* Part III.

145 *See* Faber, *supra* note 14; Molly Wanner & Neera Nathan, *Clean Cosmetics: The Science Behind the Trend*, HARV. HEALTH BLOG (Mar. 4, 2019, 10:30 AM), https://www.health.harvard.edu/blog/clean-cosmetics-the-science-behind-the-trend-2019030416066 [https://perma.cc/275B-BQFX]; *Fragrance*, CAMPAIGN FOR SAFE COSMETICS., https://www.safecosmetics.org/get-the-facts/chemicals-of-concern/fragrance/ [https://perma.cc/W5PQ-HAY8].

146 *See* Faber, *supra* note 14.

147 *See* 21 CFR § 201.63 (2021); *Smoking & Tobacco Use*, *supra* note 106; *Summary of Cosmetics Labeling Requirements*, *supra* note 60.

As demonstrated above through just a few of the labeling requirements imposed on other industries,[148] Congress and the FDA have realized the necessity of providing consumers with more information about their products. The increased understanding of the harmful chemicals within cosmetics, as well as the rise of the "clean beauty" movement, require Congress and the FDA to take similar action in the cosmetics space. A simple ingredient list is not enough to inform the general public about the health risks that cosmetic products may pose. Consumers are unable to tell whether products may be harmful to them or whether products are truly "clean" or "natural," as some labels suggest, because of the lack of standardization or definitions for these terms.[149]

While proposed laws for federal regulation of the cosmetics industry have been unsuccessful,[150] an amendment to the FD&C Act that focuses on familiar labeling requirements implemented by companies in the food and drug space and uses existing FDA rules as a guide would be a strong first step in filling the gap in the FDA's regulation of cosmetics. The methods proposed for labeling would provide for increased consumer awareness of the specific harm caused by the specific chemicals used in various products and can also reveal whether products are truly "clean," "natural," et cetera. Moreover, because strict labeling requirements already exist and have been tested for food, drugs, and tobacco products,[151] legislators may be more amenable to such changes in cosmetics regulation. Labeling requirements for cosmetics can also alleviate lawmakers' concerns about small businesses,[152] as was done with food labeling requirements.[153] Congress provided an exemption to the food labeling requirements for some small businesses, unless those businesses made specific claims relating to the nutrition of their products.[154] With a bill focused on labeling, Congress can choose to implement a similar exemption provision so that small businesses that do not make claims that their cosmetic products are "clean" or "natural" are not overburdened by regulations.

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148 *See supra* Part III.

149 *See* Burns, *supra* note 10.

150 *See supra* Section II.B.

151 *See supra* Part III.

152 *See Building Consumer Confidence by Employing the FDA to Improve Cosmetic Safety: Hearing Before the Subcomm. on Health of the Comm. on Energy and Com.*, 116th Cong. (2019).

153 *See id.*

154 *Small Business Nutrition Labeling Exemption Guidance*, FDA (Sept. 20, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-business-nutrition-labeling-exemption-guidance [https://perma.cc/5ZRM-5N4E].

V. PROPOSED LABELING REQUIREMENTS FOR COSMETICS

Due to the lack of labeling requirements imposed on cosmetics companies and the outdated system of cosmetics regulation, Congress should amend the FD&C Act.[155] An amendment should focus on familiar labeling requirements to increase consumer awareness and increase the potential for cosmetics legislation to pass through Congress. Federal legislation should 1) require causal warning labels for ingredients affecting vulnerable populations and the general population, and 2) provide definitions and standards for vague terms on cosmetics labels such as "clean," "green," and "natural." Elements of this labeling system are familiar to both the general population and the FDA, the agency that would be in charge of implementing these proposals.[156]

A. Congress should require the FDA to implement warning labels for harmful chemicals in cosmetics

Congress should amend the FD&C Act to require more than just ingredient lists for cosmetics. Like the current system for food labeling,[157] cosmetics labels should provide greater context regarding the specific harms a product can cause. Warning labels are generally effective at gaining consumers' attention[158] and are a key element of providing more information to consumers. They present the consumer with knowledge about the product that they don't currently have and can help them make informed decisions about their purchases. An FD&C Act amendment should require the FDA to implement causal warning labels due to the presence of certain ingredients in cosmetic products, as the FDA has done for tobacco products, because of the effectiveness of causal warning labels[159] and the FDA's familiarity with their implementation.[160] Because consumers might not know which ingredients in cosmetics are harmful and what harms the chemicals may pose, a list of the chemicals the product contains is not sufficient; a warning label that will allow consumers to learn more about the specific harms certain ingredients could cause is necessary. This awareness may incentivize cosmetics companies to discontinue the use of certain ingredients once consumers become aware of their harmful nature, just as consumer

155 *See supra* Part II.

156 *See supra* Part III.

157 *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

158 Argo & Main, *supra* note 121.

159 *See* Hall et al., *supra* note 108.

160 *See Cigarette Health Warnings*, *supra* note 113.

awareness caused food production companies to reduce the use of unhealthy components.[161]

Further, the warning labels will likely be even more effective considering the increased demand by consumers for more information about their cosmetic products.[162] In the past, as consumers have demanded more information and Congress has made changes in response, consumers have become more informed about how their products can impact their health. For example, when Congress worked to require packet inserts for oral contraceptives after it became clear that women received inadequate information on these drugs from their doctors, the corresponding Senate hearings and media coverage prompted increased public awareness, leading to increased public advocacy surrounding the issue.[163] Just as Congress taking action regarding information on oral contraceptives created more consumer awareness of the solution,[164] here, Congress finally taking action on cosmetics regulation will make consumers aware of labeling changes and lead consumers to both seek out and trust these labels.

First, warning labels should be implemented for vulnerable groups, such as pregnant women and their children. Just as the recent amendments regarding pregnancy labels on drugs seek to increase consumer knowledge about their potential effects,[165] labeling requirements for cosmetics should provide particular groups such as pregnant women with information on what products or chemicals may cause them harm and in what ways.[166] Labels for food are read more frequently by those with certain medical conditions, such as high cholesterol or high blood pressure.[167] Similarly, consumers with particular concerns about chemicals in cosmetics, such as pregnant women, women of color, or individuals with a family history of certain cancers, would benefit from more transparency in cosmetics labeling, which would make them aware of product ingredients that could have a particular negative effect on their health.

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161 *See* Center for Science and Democracy at the Union of Concerned Scientists, *Transparency in Food Labeling*, 2, UNION OF CONCERNED SCIENTISTS (June 2016), https://www.ucsusa.org/sites/default/files/attach/2016/07/ucs-transparency-in-food-labeling-jun2016.pdf [https://perma.cc/4FHH-G4ZS].

162 ElBoghdady, *supra* note 8 (describing an increased demand for consumer information about cosmetic contents).

163 *See* Watkins, *supra* note 94, at 23.

164 *See id.*

165 Stacey Feintuch, *FDA Says Drug Labels Must Include Clear Guidance for Pregnant Women*, HEALTHLINE (Dec. 5, 2014), https://www.healthline.com/health-news/fda-drug-labels-clear-for-pregnant-women-120514#1 [https://perma.cc/TV2W-ULVZ].

166 *See* Hall et al., *supra* note 108.

167 Center for Science and Democracy at the Union of Concerned Scientists, *supra* note 161, at 2.

Products containing chemicals that may be particularly harmful to pregnant women and their children should have a warning label that states the potential harm that a product could cause to pregnant women and their children. These labels should identify the specific chemicals in the product that might cause pregnant women harm, helping to educate consumers about unfamiliar chemicals. These labels can also be used for products harmful to young children, those with concerns about certain types of cancer due to family history, and other particularized groups.

Second, other chemicals may be deemed unsafe not just for particular groups, but for the general population. For example, an FDA study showed that talc was found to contain asbestos in 20% of cosmetic products.[168] Talc and other chemicals may pose a significant health risk to members of the general population, such as the victims in the Johnson & Johnson case,[169] and members of the public should receive warnings related to such chemicals. Other ingredients such as formaldehyde may also pose a risk to members of the general population due to their carcinogenic nature.[170] For this reason, cosmetics labels should include warnings labels for the general public regarding dangerous chemicals. This logic follows that of Congress and the FDA in implementing warning labels for some over-the-counter drugs,[171] alcohol,[172] and tobacco products, which are also designed for the general public rather than particularized groups and have been found to be effective when using strong causal language.[173]

There will certainly be disputes regarding which chemicals should receive a warning label and whether only certain quantities of a chemical or ingredient mixture should warrant a warning label. Congress may grant the FDA the authority to test the safety of cosmetic ingredients so that the FDA may determine which chemicals are most deserving of warning labels and in what quantities. Doing so would also provide support for specific causal warning statements. Additionally, the FDA should seek guidance from researchers, scientists, and industry experts. The FDA may also consider guidance from the decisions made by the European Union and Canada regarding the safety of different chemicals in certain quantities, given that they have taken far more action regarding cosmetics regulation.[174]

B. Congress should require the FDA to implement standards for

168 *FDA Tests Find Asbestos in Nearly 20 Percent of Cosmetics Products supra* note 39.

169 Rabin & Hsu, *supra* note 3.

170 *The Dirty Dozen: Formaldehyde-Releasing Preservatives*, *supra* note 27.

171 *See* 21 CFR § 201.327 (2021).

172 *See* 27 U.S.C. § 215(a).

173 *See* Hall et al., *supra* note 108.

174 *See International Laws*, *supra* note 13.

undefined terms on labels

A congressional amendment to the FD&C Act regarding cosmetics should implement specific standards for the use of terms such as "natural," "clean," "nontoxic," and "green" on cosmetic products, as well as "free from" claims, because consumers may be misled by these unstandardized terms.

The government historically created standards for product labels as consumers increasingly demand transparency, particularly in terms of the FDA and USDA's regulation of food labels.[175] The creation of these standards in the cosmetics industry is necessary to protect consumers. As consumers have become more aware of the dangers of chemicals in cosmetic products, they have begun to seek out "clean" beauty products, leading to the rise in popularity of the "clean beauty" movement.[176] However, when companies can label their products with terms such as "clean" and "natural" with no limitations on what products or chemicals can fall under those terms, consumers may be misguided by products emblazoned with these labels.[177] Some cosmetics companies have even backed efforts for increased FDA regulation, seeking more guidance in light of increasing consumer awareness of the toxic chemicals in cosmetics, and consumers' desire to purchase "clean" products.[178] Companies such as BeautyCounter have pushed for the standardization of these terms.[179] Further, the new trend of labeling products as "paraben free" may mislead consumers into thinking the product is truly clean and free of other harmful chemicals, or it may still contain some level of parabens.[180] The European Union has even banned "paraben free" claims on labels.[181] The present situation is similar to when tobacco purchasers began switching to "low" and "mild" risk products, which led the FDA to require certain standards and authorization for use of those claims.[182]

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175 *Factual Food Labels: A Closer Look at the History*, *supra* note 91.

176 ElBoghdady, *supra* note 8.

177 *Id.*

178 Animashaun, *supra* note 68.

179 *Building Consumer Confidence by Employing the FDA to Improve Cosmetic Safety: Hearing Before the Subcomm. on Health of the Comm. on Energy and Com.*, 116th Cong. (2019) (written statement of S. Gregg Renfrew, Founder and Chief Executive Officer of BeautyCounter).

180 Watson, *supra* note 72.

181 Lucy Whitehouse, *Regulation Change: The End of 'Free From' Claims for Beauty and Personal Care?*, COSMETICS DESIGN-EUROPE (June 4, 2019, 09:05 AM), https://www.cosmeticsdesign-europe.com/Article/2019/06/04/Regulation-change-the-end-of-free-from-claims-for-beauty-and-personal-care [https://perma.cc/E8UR-Q9QZ].

182 *FDA Authorizes Modified Risk Tobacco Products*, *supra* note 136.

While the warning labels proposed earlier in this Note will help to alleviate some of the issues regarding cosmetics labeling, they must be supplemented by the standardization of these "clean beauty" terms. While a warning label may indicate that there are harmful chemicals in a product, the lack of a warning label does not signify that the product is necessarily healthy or meeting consumer expectations when they read labels like "natural" or "clean."[183] Furthermore, companies might continue to label their products with these health claims while still being forced to use a warning label, particularly if the warning label is only for a vulnerable group of the population. Consumers may still be confused about the composition of their cosmetic products if they are clearly labeled with the word "clean" or "natural" on the front of the package when there is no true legal meaning for those terms in the cosmetics industry.[184]

This same issue of unsubstantiated claims prompted action in the food industry, when companies made misleading claims on their products' packaging.[185] The FDA and USDA have both developed a plethora of definitions and requirements that must be met in order for companies in the food industry to use health-related terms on their packaging.[186] These changes were also prompted by an increase in consumer demand for more transparency into the health of their food.[187] Similarly, consumers have demanded more "clean" and "natural" cosmetics.[188] The industry has responded, with many companies providing additional "clean" products alongside their typical products, but consumers may be unaware that the use of such terms is completely unregulated in the cosmetics industry.[189] Just as the FDA was concerned with the potential for misleading or under-researched claims on food products,[190] it should be concerned about cosmetics companies attempts to convince consumers to buy "clean" products with no standards or definitions. Thus, the FDA should develop clear definitions for terms such as "clean," "natural," "nontoxic," and other terms that have become more common[191] in the cosmetics industry.

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183 *See* Burns, *supra* note 10.

184 *See id.*

185 *Factual Food Labels: A Closer Look at the History*, *supra* note 91.

186 *See* 21 CFR §§ 101.54–101.69 (2021); U.S. DEPARTMENT OF AGRICULTURE, A GUIDE TO FEDERAL FOOD LABELING REQUIREMENTS FOR MEAT, POULTRY, AND EGG PRODUCTS, *supra* note 128.

187 *Factual Food Labels: A Closer Look at the History*, *supra* note 91.

188 *See* Dina ElBoghdady, *supra* note 8.

189 *See id.*

190 *See id.*

191 *See id.*

For consumers, understanding such definitions was likely not as difficult for food purchases because it is easier to interpret a "low fat" or "no sugar" label. Here, without clear definitions, consumers are unable to differentiate between the various vague terms used in cosmetics packaging, instead assuming that they must be safe, or at least safer relative to other products without any such label.[192] The NLEA requires that the definition of standardized terms appear on food packaging to ensure that consumers understand the meaning of the label and standard.[193] Requiring cosmetics companies to include the definition on the packaging of any such term they use, as defined by the FDA, will provide consumers with greater transparency regarding the types of ingredients used in their products and how these ingredients can impact their health. The definition of each standardized term used by the company on the label should appear on the back of the product so that consumers can see and understand what each label means when they consider making their purchase and compare various products.

The creation of these standards for cosmetic products can mimic the creation of standards for terms in food labeling by the FDA in the rulemaking process.[194] When implementing the NLEA, the FDA sought and received comments from consumers, health experts, consumer advocacy groups, members of the industry, and state and local governments.[195] To develop a better understanding of how consumers might view the terms that the FDA seeks to standardize, the FDA should look to consumer advocacy groups in particular. The FDA can learn from groups that have developed guides for consumers regarding how to evaluate the safety of their cosmetics. For example, the Environmental Working Group has created in-depth criteria for cosmetic products marked "EWG Verified" in on their website.[196] The Environmental Working Group falls under a coalition of groups in the Campaign for Safe Cosmetics,[197] members of which might be willing to provide guidance as to the key areas of consumer concern regarding unstandardized terms.

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192 *See* Burns, *supra* note 10.

193 INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, *supra* note 90, at 29.

194 *Id.*

195 Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2079 (Jan. 6, 1993).

196 *GET TO KNOW: EWG's Criteria*, ENV'T WORKING GRP., https://www.ewg.org/ewgverified/standards.php [https://perma.cc/N27Q-TV55].

197 *About Us*, CAMPAIGN FOR SAFE COSMETICS, https://www.safecosmetics.org/about-us/ [https://perma.cc/J467-LH4K].

CONCLUSION

Until the FDA imposes stricter labeling requirements on cosmetics companies, consumers will be ill-informed regarding the harmful chemicals present in many of the products that they purchase and whether the "clean beauty" products they use are truly clean. This lack of consumer awareness can have a harmful impact on the general population, as well as vulnerable groups such as pregnant women and children. The proposed changes to the FDA's labeling of cosmetics are quite familiar to the average population, Congress, and the FDA because they mirror those implemented in the food, drug, tobacco, and alcohol industries. An FD&C Act amendment that focuses on labeling will allow for increased consumer knowledge regarding the composition of cosmetic products. This amendment to the cosmetics regulation portion of the FD&C Act should require the FDA to: 1) order warning labels for both vulnerable groups and the general population and, 2) standardize terms used on cosmetics labels, such as "natural" and "clean." Only after the FDA imposes these labeling requirements will consumers of cosmetics be equipped to make informed choices about their health, just as they are with their choice of food, medication, and other commonly used products.