

The Safe Cosmetics Act of 2011 (H.R. 2359): Implications for the Cosmetics Industry

BY DENNIS S. ELLIS, ADAM M. REICH & LILLIAN CHU

The Safe Cosmetics Act of 2011 (H.R. 2359): Implications for the Cosmetics Industry

Regulation of the cosmetics industry has garnered significant national attention in recent months. On March 27, 2012, nine months after legislators introduced the Safe Cosmetics Act of 2011, H.R. 2359, a subcommittee of the U.S. House of Representatives convened a hearing about the “current state of cosmetics.”¹ One day earlier, Reps. Dingell (D-MI) and Pallone (D-NJ) introduced a similar legislative bill, the Cosmetics Safety Enhancement Act, H.R. 4262. And just last April, Rep. Lance (R-NJ) introduced the Cosmetic Safety Amendments Act of 2012, H.R. 4395. While each of these bills is slightly different, their collective introduction is indicative of a referendum for reform that could profoundly impact the cosmetics industry.

This Client Alert discusses the current regulatory framework for cosmetics, analyzes the Safe Cosmetics Act of 2011, the bill that seemingly prompted the March 2012 House hearing and introduction of the two other bills, and offers related best practices and compliance advice to cosmetics companies. Today’s cosmetics are not regulated rigorously by the federal government, as the Food, Drug, and Cosmetic Act of 1938 (“FDCA”) only requires the U.S. Food and Drug Administration (“FDA”) to monitor cosmetics.² States have taken steps to fill this space, passing divergent, sometimes conflicting, regulatory measures, which subject cosmetics companies to ambiguous responsibilities and a risk of litigation. The Safe Cosmetics Act of 2011 would, for the first time, set a national safety standard for cosmetics, including strict labeling, reporting, and testing requirements. Thus, it is critical that cosmetics companies understand the nuances and implications of this proposed legislation.

Lipstick Jungle Demystified: The Current Regulatory Framework for Cosmetics

Modern cosmetics, with their pharmaceutical-type properties and drug-like ingredients, are poles apart from the cosmetics sold in 1938, when Congress passed the FDCA. In the past, cosmetics offered temporary, superficial alterations.³ Today, cosmetics contain drug-like ingredients and are marketed as “treatments” and “serums,” capable of “ultra correction” and “rescue.”⁴ While cosmetics have evolved, federal law has not. Consequently, when consumers allege injury from alpha-hydroxy acids in creams, lead in lipsticks, or formaldehyde in hair treatments, cosmetics companies face the prospect of multiple punishments for the same alleged harm.

Federal Regulation of Cosmetics

The federal law that confers “regulatory powers” for cosmetics on the FDA provides scant authority. While the FDCA prohibits adulteration and misbranding of cosmetics, it does not oblige cosmetics companies to submit proposed products or components, other than color additives, for pre-market review and approval; to register with the FDA; or to advise the FDA of product ingredients pre-market

introduction.⁵ Further, the FDCA does not set forth good manufacturing practice requirements for cosmetics.⁶ In short, the FDCA's blunted language makes the FDA a reactive federal agency, dependent upon post-market release consumer complaints and the cosmetic industry's voluntary provision of information.⁷

State Regulation of Cosmetics

States have acted to fill the perceived vacuum created by the FDCA, passing statutes to address cosmetics. Many of these laws do no more than echo or support enforcement of the FDCA.⁸ However, some states have passed more comprehensive regulations. In California, for example, the California Safe Cosmetics Act of 2005 ("CSCA") compels manufacturers to advise state regulators about cosmetics that "contain any ingredient that is a chemical identified as causing cancer or reproductive toxicity," including chemicals used for fragrance or flavoring.⁹ The CSCA also grants the state broad investigative authority for cosmetics containing "ingredients of concern," including the power to order manufactures to submit data about health effects and related studies.¹⁰ Meanwhile, in Washington, the Children's Safe Products Act of 2008 restricts the use of phthalates in cosmetics made for or marketed to children, and permits the state to force manufacturers to generate reports about cosmetics containing "high priority" chemicals.¹¹ As another example, New York has passed a statute that restricts the amount of volatile organic compounds, which may be included as ingredients in cosmetics.¹²

The Safe Cosmetics Act of 2011: Background

On June 24, 2011, U.S. Representatives introduced the Safe Cosmetics Act of 2011, H.R. 2359, to "ensure the safe use of cosmetics."¹³ The Act's provisions include:

- Annual registration requirements for companies with more than \$2 million in sales, accompanied by fees for companies manufacturing or packaging cosmetics that have annual gross receipts or sales exceeding \$10 million;¹⁴
- Disclosure requirements that obligate cosmetics manufacturers to submit to the U.S. Department of Health and Human Services ("HHS"): ingredient lists; product warnings; directions for use; and "all [accessible cosmetic safety] data and information;"¹⁵
- New product label requirements requiring cosmetics manufacturers to identify all ingredients; mandating that Internet vendors display ingredient lists; and vitiating trade secrets protections for cosmetics companies' ingredient identities;¹⁶
- Broad public disclosure requirements compelling companies to disclose: the name, identity, structure, and function of all cosmetic ingredients; the potential hazards to health and the environment posed by cosmetics; and the fragrance, flavor, and colorants used in cosmetics;¹⁷
- A process for cosmetics companies to petition HHS to keep information confidential, which requires petitioners to satisfy a high burden of proof, but prohibits them from blocking disclosure of the name, identity, structure, and related health and safety data of any chemical substance, contaminant, or impurity that is a cosmetic ingredient;¹⁸
- Mandatory adverse health effects reporting requirements, including identification of any individuals experiencing adverse health effects as a result of use of a cosmetic;¹⁹
- Expanded lawmaking responsibilities for HHS, including promulgation of: labeling requirements; safety standards; cosmetic contaminant testing protocols; and good manufacturing practices guidance;²⁰

- Listing duties for HHS regarding cosmetics and ingredients, including creation of: (1) a “prohibited and restricted” list; (2) a “safe with limits” list; (3) a “priority assessment” list; and (4) a list of cosmetics or packaging ingredients that may contain contaminants;²¹
- A “Savings Clause” permitting states to adopt or enforce regulations that are more stringent than the Safe Cosmetics Act of 2011, including broader warning labels;²² and
- Potent recall authority for HHS, such that HHS can recall or cease distribution of any cosmetic, and only have its order vacated if the impacted company files an appeal within 24 hours of issuance of such an order.²³

The Safe Cosmetics Act of 2011: Is It “Safe” For the Cosmetics Industry?

The Safe Cosmetics Act of 2011 would alter the cosmetics regulatory landscape, but whether its enactment would actually benefit consumers and the cosmetics industry is debatable. On the one hand, the Safe Cosmetics Act of 2011 has the positive effect of mandating greater industry transparency. Improved transparency should lead to expanded consumer knowledge and minimize the number of products liability lawsuits predicated on non-disclosure of harmful ingredients. Similarly, expanded consumer knowledge should strengthen cosmetics companies’ assumption of risk and comparative fault defenses against product liability suits, as consumers would know every component that a cosmetic contains at the time of purchasing.²⁴ In addition, because the Safe Cosmetics Act of 2011 obligates manufacturers to submit product warning labels to HHS for review and approval, there may be a decline in the amount of “failure to warn” products liability suits.²⁵ Further, improved transparency would also allow manufacturers to include new fragrance or flavor components that they may have previously foresworn because of uncertainty about constituent ingredients, thereby expanding companies’ product portfolios. Finally, the Act’s transparency requirements would also allow cosmetics companies to avoid ingredients revealed to contain potentially harmful constituents, thus mitigating litigation risk.

The mandatory uniform contaminant standards and testing protocols included in the Safe Cosmetics Act of 2011 may also benefit cosmetics companies. The Act would assuage cosmetics companies’ concerns about drastically inconsistent obligations in different states and should reduce the number of products liability lawsuits filed against them. Moreover, consumer confidence in product safety would likely improve as a result of the imposition of uniform federal standards and testing protocols, leading to an increase in sales.

While the Safe Cosmetics Act of 2011 has the potential to benefit consumers and the cosmetics industry, there may also be unintended consequences if the Act is passed. For one thing, any testing obligations imposed by HHS without input from cosmetics companies may, in effect, create a new layer of costly testing that does not improve overall safety.²⁶ Cosmetics companies have had years to hone their product knowledge, and they understand the cosmetics that they manufacture better than HHS. Further, because cosmetics companies face liability for misbranding if they fail to substantiate product safety prior to market introduction, cosmetics companies are already incentivized to use the most unassailable safety tests possible.²⁷ Hence, any tests that HHS mandates may be unnecessarily cumulative. Another side-effect of the Safe Cosmetics Act of 2011 may be the imposition of a significant financial burden on cosmetics companies as they bring their practices and products into compliance with the Act’s extensive disclosure and testing requirements. HHS’ promulgation of new rules could exacerbate this burden, particularly if HHS compels companies to engage in the daunting exercise of determining and disclosing percentage breakdowns of various cosmetic components and constituent ingredients to the “nth degree.”

Yet one more significant potential repercussion of the Safe Cosmetics Act of 2011 is the loss of competitive advantage. Specifically, the Act’s ingredient disclosure requirements might lead cosmetics companies to lose market share and face increased litigation. Cosmetics companies presently enjoy

trade secret protection for their product formulations.²⁸ Disclosures required by the Safe Drug Act of 2011 would vitiate these protections, as companies would no longer be able to keep secret the components of their trade formulations.²⁹ With access to knowledge about competitor ingredients, more companies will be able to make essentially the same products, leading to expanded choice in the marketplace and loss of sales by the disclosing company. Once competitors begin creating a copycat product featuring the discloser's ingredients, litigation based in antitrust and intellectual property law will inevitably follow.

Lastly, three further possible unforeseen effects of the Safe Cosmetics Act of 2011 are worth noting. First, the requirement that cosmetics' labels list ingredients with unfamiliar names might cause consumer confusion. Parallel issues arose when Congress first discussed the Fair Packaging and Labeling Act, 15 U.S.C. § 1451 *et seq.*, and after considerable debate, Congress ultimately settled on a much reduced list. It is unclear whether Congress will act similarly with the Safe Cosmetics Act of 2011. Second, the Act's Savings Clause, which allows states to pass more stringent regulations and impose additional labeling requirements, condones the problem of inconsistent obligations in different states.³⁰ Third, the Savings Clause may perpetuate rather than reduce the number of "failure to warn" products liability suits, because the Safe Cosmetics Act of 2011 permits states to impose harsher product warning requirements than HHS.³¹ Thus, while the Safe Cosmetics Act of 2011 will set a stricter federal regulatory standard, preempting less restrictive, inconsistent state legislation, states will still be able to pass laws that impose added financial burdens and litigations risks.

In short, the Safe Cosmetics Act of 2011 stands to dramatically change the cosmetics regulatory world and cosmetics companies will face new burdens as a result.

The Safe Cosmetics Act of 2011: Practical Implications and Keys to Compliance

If Congress passes the Safe Cosmetics Act of 2011, cosmetics companies must be prepared for the new regulatory world that will emerge. Opportunistic plaintiffs may file class action lawsuits seeking to "cash in" on a cosmetic company's failure to timely and strictly comply with the new regulations. Further, the Safe Cosmetics Act of 2011 might even spawn competitor cases when a company releases a product featuring the same ingredients as one of its rival's products. The more companies learn at present, the better their chances of timely compliance with the Safe Cosmetics Act of 2011's labeling and disclosure requirements, and the greater the likelihood of avoiding lawsuits alleging non-compliance. Furthermore, companies who spend time and money today to learn about product ingredients and design expanded packaging capable of including appropriate ingredient lists will be better positioned to defend against lawsuits in the future, having adequately warned consumers regarding risks associated with using their products.

To protect market share and intellectual property in a post-Safe Cosmetics Act of 2011 world, cosmetics companies should establish an approach to document and prove independent creation of their products at all levels. Proof of independent development and creation will help to defeat misappropriation of trade secrets claims.³² In addition to laying foundation for a sturdy litigation defense, cosmetics companies should also devise a proactive strategy for monitoring competitor product ingredients and protecting company intellectual property.

Cosmetics companies also need to reevaluate company practices. Since all cosmetics companies will have access to competitor ingredients lists if Congress passes the Safe Cosmetics Act of 2011, manufacturers may want to reconsider their marketing efforts, including branding and packaging, so that they can better stand out against what may eventually be equivalent products. Further, cosmetics companies should also seek counsel from attorneys proficient in regulatory compliance that can help companies reduce unnecessary spending, devise a strategy for conformity, and avoid potential fines and/or consumer litigation.

Finally, because the Safe Cosmetics Act of 2011 only permits cosmetics companies 24 hours to appeal a recall order, and, at most, five days from issuance of that order to be heard on the matter, cosmetics companies should spend time now, before the Act is passed, identifying and retaining counsel who is experienced and knowledgeable regarding the evolving regulatory landscape. Competent counsel would include attorneys who are familiar with the Safe Cosmetics Act of 2011, cognizant of the affected company's products and product ingredients, and capable of succeeding under such time-restrictive deadlines.

Conclusion

The Safe Cosmetics Act of 2011 would bring about the first significant change to federal cosmetics industry regulation in nearly 75 years, and preempt inconsistent, less stringent state laws. Its passage should benefit cosmetics companies currently subjected to incompatible state statutes by setting a uniform federal standard. Yet, despite its significant advantages, there are some drawbacks to the Safe Cosmetics Act of 2011, including: a potentially high financial cost of compliance; possible lofty registration fees for companies with annual gross receipts or sales of cosmetics that exceed \$10 million; prospective decline in product sales and loss of market share as a result of ingredient disclosure and labeling requirements; and a possible increase of litigation expenses for those companies that do not act now to be in a position to timely comply with the law. Considering these potential ramifications, cosmetics companies would be wise to scrutinize their cosmetics and product ingredients, and reevaluate their budgets and business practices today. In particular, cosmetics companies need to be prepared to aggressively protect their products and market share, and to that extent, should identify competent counsel to assist them in their efforts.

Mr. Ellis has represented several cosmetic companies and cosmetic related companies for over 10 years. If you have any questions concerning these developing issues, please do not hesitate to contact Mr. Ellis directly as follows:

Los Angeles

Dennis S. Ellis
1.213.683.6264
dennisellis@paulhastings.com

¹ Examining the Current State of Cosmetics: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce, 112th Cong. (2012).

² Pub. L. No. 75-717, § 201(g), (h), 52 Stat. 1040, 1041 (codified as amended at 21 U.S.C. § 321(g), (h) (1994)).

³ Compare 21 U.S.C. § 321(i) (defining "cosmetic" as "articles" and "components" thereof "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance") with 21 U.S.C. § 321(g)(1) (defining "drug" as "articles" intended for "cure, mitigation, [and] treatment" and "to affect the structure or any function of the body").

⁴ E.g., Kiehl's "Creamy Eye Treatment with Avocado," which has been subjected to tests by physicians; Artistry's "Essentials Alpha Hydroxy Serum Plus;" Chanel's "Ultra Correction Line Repair Anti-Wrinkle Day Cream SPF 15;" and Jack Black's "Protein Booster Eye Rescue" featuring "the PureScience® Formula."

⁵ 21 U.S.C. §§ 361, 362, 379(e) (2012). See also Laura A. Heyman, The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids, 52 Food & Drug L.J. 357, 363-64 (1997).

⁶ Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?), U.S. FDA, July 8, 2002, available at <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm> (last visited on Apr. 3, 2012).

⁷ 21 C.F.R. §§ 710, 720 (2012) (Voluntary Cosmetic Registration Program).

⁸ See, e.g., 410 Ill. Comp. Stat. § 620/21 (2011) (adopting the FDCA); Ind. Code § 16-42-1-1 (2011) (indicating intention that state regulations be "uniform with the [FDCA]"); Mass. Gen. Laws ch. 94 §§ 186-187 (2012) (importing language

from the FDCA); N.D. Cent. Code §§ 19-02.1-17 – 18 (2011) (same); S.C. Code Ann. § 39-25-180 (2011) (adopting the FDCA); N.C. Gen. Stat. § 106-139 (2011) (granting state agencies the authority to promulgate regulations to enforce the FDCA).

⁹ Cal. Health & Safety Code § 111792(a) (2006).

¹⁰ Id. at § 111792.5.

¹¹ Wash. Rev. Code Ann. §§ 70.240.020-70.240.040 (2011).

¹² N.Y. Comp. Codes R. & Regs. tit. 6, § 235-2.1 (2012).

¹³ The Safe Cosmetics Act of 2011, H.R. 2359, 112th Cong. (2011).

¹⁴ Id. at § 612.

¹⁵ Id. at §§ 615, 619.

¹⁶ Id. at § 613.

¹⁷ Id. at § 623.

¹⁸ Id.

¹⁹ Id. at § 622.

²⁰ Id. at §§ 613-614.

²¹ Id. at §§ 616, 618, 627.

²² Id. at § 628.

²³ Id. at § 620.

²⁴ See Am. L. Prod. Liab. 3d § 41:36 (2012) (discussing assumption of risk and comparative fault); 72A C.J.S. Products Liability § 77 (2012) (same).

²⁵ See id. at § 619(a)(6) (discussing warning reporting requirements); *Jack v. Alberto-Culver USA, Inc.*, 06-1883 (La. 2007), 949 So. 2d 1256, 1257 (indicating that a consumer cannot prevail on a failure to warn suit if the cosmetics manufacturer used reasonable care in providing the warning); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (indicating that FDA-approved labeling may preempt products liability claims based on failure to warn). But see H.R. 2359 at § 628 (permitting states to impose potentially more stringent warning requirements than the Safe Cosmetics Act of 2011, and thus providing plaintiffs a counterargument to preemption defenses).

²⁶ See Roseann B. Terminin & Leah Tressler, *American Beauty: An Analytical View of the Past and Current Effectiveness of Cosmetic Safety Regulation and Future Direction*, 63 Food & Drug L.J. 257, 265 (2008) (noting that cosmetics companies publish safety test results in well-known peer reviewed scientific literature); *Smallwood v. Clairol, Inc.*, No. 03 Cv. 8394 (SWK), 2005 U.S. Dist. LEXIS 2726, at *1 (S.D.N.Y. Feb. 18, 2005) (supporting the soundness of cosmetics industry safety tests by rejecting a products liability suit related to a hair coloring product because the plaintiff had not followed the manufacturer-recommended “patch test” product application, and because the plaintiff’s alleged allergic reaction was the only one reported out of 7.7 million products shipped); *Thomas v. Gillette Co.*, 230 So. 2d 870, 870-71 (La. App. 1970) (refusing to find cosmetics company’s product testing negligent).

²⁷ See 21 C.F.R. § 740.10 (2012) (failure for “each finished cosmetic product [to] be adequately substantiated for safety prior to marketing” may result in punishment for product misbranding).

²⁸ See Restatement of Torts § 757 cmt. b (1939 Supp. 2011) (“A trade secret may consist of any formula . . . or compilation of information which is used in one’s business, and which gives him an opportunity to obtain advantage over competitors who do not know or use it.”); *Phillips v. Frey*, 20 F.3d 623, 628 (5th Cir. 1994) (a manufacturing process is a trade secret); *SI Handling Sys., Inc. v. Heisley*, 753 F.2d 1244, 1261 (3d Cir. 1985) (“formulae used in [] design are clearly at the very core of trade secret law protection”); *FMC Corp. v. Taiwan Tainan Giant Indus. Co.*, 730 F.2d 61, 63 (2d Cir. 1984) (“formulae for compounds” are protected trade secrets).

²⁹ See, e.g., *Pioneer Hi-Bred Int’l v. Holden Found. Seeds, Inc.*, 35 F.3d 1226, 1235 (8th Cir. 1994) (“Fundamental to the existence of a trade secret is that the matter be, in fact, secret.”); *Sheets v. Yamaha Motors Corp.*, U.S.A., 849 F.2d 179, 183-84 (5th Cir. 1988) (“A disclosure of a trade secret to others who have no obligation of confidentiality extinguishes the property right in the trade secret”); *Self Directed Placement Corp. v. Control Data Corp.*, 908 F.2d 462, 465 (9th Cir. 1990) (no trade secret protections for items of “public knowledge”).

³⁰ See Id.

³¹ Id.

³² See, e.g., *Moore v. Kulicke & Soffa Indus., Inc.*, 318 F.3d 561, 567-68 (3d Cir. 2003); *Reingold v. Swiftships, Inc.*, 126 F.3d 645 (5th Cir. 1997).

Paul Hastings LLP

www.paulhastings.com

StayCurrent is published solely for the interests of friends and clients of Paul Hastings LLP and should in no way be relied upon or construed as legal advice. The views expressed in this publication reflect those of the authors and not necessarily the views of Paul Hastings. For specific information on recent developments or particular factual situations, the opinion of legal counsel should be sought. These materials may be considered ATTORNEY ADVERTISING in some jurisdictions. Paul Hastings is a limited liability partnership. Copyright © 2012 Paul Hastings LLP.

IRS Circular 230 Disclosure: As required by U.S. Treasury Regulations governing tax practice, you are hereby advised that any written tax advice contained herein or attached was not written or intended to be used (and cannot be used) by any taxpayer for the purpose of avoiding penalties that may be imposed under the U.S. Internal Revenue Code.