

Cosmetics And Beauty Product Litigation



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Meryl C. Maneker and Vickie E. Turner

Use of beauty products and cosmetics is on the rise — and so is the litigation over them.

IT IS ESTIMATED THAT Americans spent approximately \$50 billion on cosmetics and toiletries in 2006. Natasha Singer, *Should You Trust Your Makeup?*, N.Y. Times, Feb. 15, 2007. In that same year, approximately 11 billion personal care products, a term now commonly used to refer to cosmetics, toiletries, fragrances, and beauty products, were sold. Roseann B. Termini and Leah Tressler, *American Beauty: An Analytical View of the Past and Current Effectiveness of Cosmetic Safety Regulations and Future Direction*, 63 Food & Drug L.J. 257, 273 (2008). Globally, personal care products generate more than \$250 billion annually in retail sales. Personal Products Care Council, "About Us" page, available at www.personalcarecouncil.org. In one recent survey, the average responding adult reported using nine personal care products each day. Environmental Working Group, Comments for Public Meeting on International Cooperation on Cosmetics Regulations ("ICCR") Preparations Before the U.S. Food and Drug Admin. (June

19, 2008) (hereinafter Env't Working Group, Comments for Public Meeting), available at www.cwg.org/node/26733. Not only do these statistics reflect extensive purchasing and use of cosmetic and beauty products but, by all reports, these numbers are increasing. Moreover, unlike drugs and medical devices, almost every American uses a personal care product and, also unlike most drugs and medical devices, the use of lotions, shampoos, and other such products is mostly optional. Thus, the potential for litigation in the area of cosmetics and beauty products is great.

REGULATORY FRAMEWORK OF COSMETICS AND BEAUTY PRODUCTS: FOOD, DRUG, AND COSMETIC ACT GENERALLY

• On the federal level, cosmetics are regulated pursuant to the Food, Drug, and Cosmetic Act ("FD&CA") 21 U.S.C. §301 et seq. Cosmetics were not included in the original food and drug legislation enacted by Congress in the early 20th Century. However, with the advent of the manufacturing of cosmetics and the increased acceptance of their use, cosmetics products gained significant market share around World War I. Termini and Tressler, *supra*, at 258-59. After widespread reports of injuries from products like depilatory creams and eyebrow tints, concerns regarding the potential negative health effects of cosmetic products grew along with corresponding demands for regulation, and in 1938 the Food and Drug Act was amended to become the Food, Drug, and Cosmetic Act of 1938. *Id.* Under the law, which has not been changed significantly since its original enactment, manufacturers are prohibited from selling adulterated or misbranded cosmetics in interstate commerce. 21 U.S.C. §331(a).

FDA Oversight

Under the FD&CA, a cosmetic is defined as any article "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beau-

tifying, promoting attractiveness, or altering the appearance." 21 U.S.C. §321(i). The federal Food and Drug Administration ("FDA"), the agency responsible for enforcement of the FD&CA, considers products such as "skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, and deodorants" to be cosmetics. Center for Food Safety and Applied Nutrition, Food and Drug Administration, *Is It a Cosmetic, a Drug, or Both? (or Is It Soap?)* (July 8, 2002, updated April 30, 2012), available at www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm. Generally, the level of governmental oversight over cosmetics is significantly less than that given the development and marketing of pharmaceuticals and medical devices. The most notable difference is that, with the exception of color additives, the FD&CA provides no authority for the FDA to review cosmetics before they are marketed and, thus, the FDA does not test or approve cosmetics prior to their being sold to consumers. Food and Drug Administration, *FDA Authority Over Cosmetics* (Mar. 3, 2005), available www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074162.htm. In addition, while drug manufacturers must submit evidence of the safety and effectiveness of their products before they are sold, cosmetic manufacturers themselves are responsible for establishing the safety of their own products. However, if a manufacturer has "not adequately substantiated prior to marketing" that its cosmetic is safe, the manufacturer must provide a warning of the lack of safety testing. 21 C.F.R. §740.10(a). The FDA also does not have authority to order a recall of a cosmetic.

The primary oversight of cosmetics by the FDA is to ensure that the cosmetics on the market are not adulterated or misbranded. "A cosmetic shall be deemed to be adulterated ... if it bears or contains any poisonous or deleterious substance" that can injure those who use it as intended. 21 U.S.C.

§361(a). A cosmetic is also adulterated if it consists “of any filthy, putrid or decomposed substance,” or it was “prepared, packed or held under unsanitary conditions” that would make it “injurious to health.” 21 U.S.C. §361(b) and (c).

While the prohibition against adulteration focuses on the substance of the product, the prohibition against misbranding focuses on the product’s labeling. A cosmetic is misbranded if it is “improperly labeled or deceptively packaged.” *FDA Authority Over Cosmetics*, supra. Specifically the FD&CA defines a product as misbranded if “its labeling is false or misleading,” its label does not contain the name and address of the manufacturer or distributor and “an accurate statement of the quantity of the contents,” the label omits any other information required by the FDA, or if the container is misleading. 21 U.S.C. §§362(a)-(d). The labeling on cosmetics must also comply with the requirements of the Poison Prevention Packaging Act of 1970 and, if the product contains color additives, the label required for those. *Id.* at §362(e).

Fair Packaging And Labeling Act

The other major statute governing cosmetics is the Fair Packaging and Labeling Act of 1973 (“FPLA”), 15 U.S.C. §1451, which requires ingredient statement labels on all consumer products and that the ingredients be listed in order of predominance. The FDA considers cosmetics that do not comply with the FPLA to be misbranded. *FDA Authority Over Cosmetics*, supra.

In order to obtain information regarding the cosmetics on the market and the entities that manufacture them, the FDA operates the Voluntary Cosmetic Regulation Program (“VCRP”). *See* Food and Drug Administration, Voluntary Cosmetic Registration Program (Nov. 15, 2012), available at www.fda.gov/Cosmetics/Guidance/ComplianceRegulatoryInformation/default.htm. There are two components of the VCRP and, in keeping with the largely self-regulatory approach to

oversight of cosmetics, manufacturers may participate in either or both. 21 C.F.R. pts. 710 and 720. The first part of the program is the registration of manufacturing locations of cosmetics distributed in the United States. The second component is the filing of a Cosmetic Product Ingredient Statement for each product distributed. The FDA uses the VCRP as a “post-market reporting system.” *Id.*

As noted, color additives are governed by a somewhat different regulatory scheme. These are the only portions of cosmetic products for which FDA approval must be obtained from the FDA. *FDA Authority Over Cosmetics*, supra.

INCREASED STATE OVERSIGHT OF COSMETICS AND BEAUTY PRODUCTS •

While the federal statutory framework governing cosmetics has remained relatively unchanged for the last 70-plus years, the technology and science used in the creation and manufacture of personal care products has developed and changed considerably in this same time period. It is possibly for this reason that cosmetics and beauty products have received increasing amounts of attention from state legislators and regulators, who often note a perceived lack of necessary oversight on the federal level.

California Safe Cosmetics Act

For example, in 2005, California passed the California Safe Cosmetics Act. California Safe Cosmetics Act, Cal. Health & Safety Code §111791. In enacting the statute, the California legislature specifically noted the lack of federal “premarket safety testing, review or approval of cosmetic products” and the fact “the FDA does not have the authority to require manufacturers to file health and safety data on cosmetic ingredients or to order a recall of a dangerous cosmetic product,” presumably as reasons that legislation on the state level was needed. 2005 Cal. Stat. ch. 729, §1(b) & (c). The California legislature also noted that “[i]ndependent testing in the United States and the European Union has

determined that some cosmetic products contain substances known or suspected to cause cancer and reproductive toxicity.” *Id.* The legislature then cited its belief that “[c]osmetic products are most heavily used by women of childbearing age,” and stated its concern for the health and safety of beauty care workers who are primarily women and minorities. 2005 Cal. Stat. ch. 729 at §1(a), (e) & (f). Finally, California’s legislators noted the existence of “[a]lternatives to substances that cause[d] cancer or reproductive toxicity” and that are “readily available for use in cosmetic product.” *Id.* §1(i).

As a result, effective January 1, 2007, cosmetics manufacturers selling products in California must identify to the state any cosmetic product “sold in the state ... and that contain[s] any ingredient that is a chemical identified as causing cancer or reproductive toxicity....” Cal. Health & Safety Code §111792(a). Notably, California’s legislation applies to chemicals used for fragrance or flavoring. Cal. Health & Safety Code §111792 (a)(1). This is in contrast to federal law that does not require that ingredients used for fragrance or flavoring be identified on packaging. 21 C.F.R. §701.3. In addition, the state is authorized to “conduct an investigation of one or more cosmetic products that contain chemicals identified as causing cancer or reproductive toxicity.” Cal. Health & Safety Code §111792.5(a). In recent years similar legislation has been proposed in Washington State, Colorado, New York State, and New York City. Note, *Concealing Danger: How the Regulation of Cosmetics In The United States Puts Consumers At Risk*, 23 Fordham Env’tl. L. Rev. 203, 254-269 (2012).

Since 2007, California has identified five additional chemicals that trigger the Act’s mandatory reporting requirements, notified 7,000 manufacturers that they were out of compliance with the Act’s provisions, and made the reporting system available online. *Id.* at 256. In addition, and perhaps more notably, pursuant to the Act, the California Attorney General obtained an injunction against

the manufacturer of a Brazilian hair relaxing treatment, “Brazilian Blowout,” that emits formaldehyde gas, and obtained \$600,000 in fees and penalties and an agreement to provide a warning in a subsequent settlement. Andrew Martin, *Maker of Hair-Straightening Product Settles Lawsuit*, N.Y. Times, March 6, 2012.

Safety Concerns

One factor leading to the enactment of legislation governing cosmetics on the state level is the increasing emphasis being placed on cosmetic safety by environmental, health and safety, and consumer advocacy groups. Increasing concerns in this area have led to a debate on whether the FDA should increase its oversight of cosmetic manufacturing and sales. The calls for greater governmental oversight of cosmetics, based in large part on claimed threats to health and safety will, in all likelihood, be accompanied by an increase in litigation regarding these products. Two of the areas likely to be the subject of such litigation are the safety of particular ingredients used in the formulation of cosmetics and beauty products, and challenges to claims made in the marketing of these products.

ISSUES RELATED TO INGREDIENTS OF COSMETICS AND BEAUTY PRODUCTS

- Increasingly, the individual ingredients used in cosmetics are being scrutinized. This approach is significant given the large number of ingredients in cosmetics and beauty products. The survey that found an average adult uses nine personal care products daily also identified “126 unique chemical ingredients” in personal care products. Env’tl Working Group, Comments for Public Meeting, *supra*

The cosmetic industry has historically addressed the safety of cosmetic ingredients through the Cosmetic Ingredient Review (“CIR”) Program. Established in 1976 and operated by the Personal Care Products Council (“PCPC”), the major trade

association in the industry, the CIR Program utilizes an expert panel that assesses the safety of cosmetic ingredients. The CIR then provides the results of these assessments in peer-reviewed journals. According to the PCPC, the CIR Expert Panel has reviewed the safety of approximately 1,500 cosmetic ingredients. News Release, *Personal Care Products Council Announces Significant Advances in the Cosmetic Ingredient Review (CIR) Program* (June 4, 2008), available at www.newspicker.org/6202/personal-care-products-coouncil-announces-significant-advances.

Recently, however, criticisms have been leveled both at the scope and effectiveness of the CIR Program. According to one consumer group, as of a few years ago, only 11 percent of all cosmetic ingredients have been reviewed under this program. Env't'l Working Group, Comments for Public Meeting, *supra*. According to the Environmental Working Group, only 1,400 of an estimated 12,500 ingredients have been reviewed. More importantly, both the FDA and the CIR have been roundly criticized for only prohibiting a handful of ingredients though numerous products on the market in the United States contain chemicals banned from cosmetics in other countries. *Id.*; see also Tim Little, Sanford Lewis and Pamela Lundquist, *Beneath The Skin: Hidden Liabilities, Market Risk and Drivers of Change in the Cosmetics and Personal Care Products Industry*, (2007), available at www.iehn.org/filesalt/IEHNCosmeticsReportFin.pdf, (noting that the European Union bars more than 1,000 chemicals from use in cosmetics sold in the E.U.) Env't'l Working Group, Comments for Public Meeting, *supra*. The discussion below focuses on just a handful of the ingredients that can be found in cosmetic and beauty products. One advocacy group has identified more than 8,800 “unique ingredients” in cosmetic products sold in the United States, and the FDA itself estimates there are 12,500 different cosmetic ingredients. Env't'l Working Group, Comments for Public Meeting, *supra*. With the increased focus by consumers, advocacy organizations, and govern-

mental agencies on the safety of ingredients, comes the possibility for increased litigation as well.

Lead In Lipstick

A good example of greater focus on cosmetic ingredients is lead in lipstick. In October 2007, the Campaign for Safe Cosmetics, a coalition of health and safety and consumer groups organized to address health issues related to the use of cosmetics, reported finding detectable levels of lead in more than half of 33 lipsticks it had tested. Campaign for Safe Cosmetics, *A Poison Kiss: The Problem of Lead in Lipstick* (Oct. 11, 2007), available at www.safecosmetics.org/downloads/A%20Poison%20Kiss_report.pdf (see page 10). The amount of lead ranged from .001 to .65 parts per million (“ppm”). While not declaring the products a health risk outright, the report claimed that “lead-containing lipstick applied several times a day ... could add up to significant exposure levels.” *Id.* at 2. The report also contrasted the levels of lead found in the lipstick with the permissible level of lead set by the FDA for candy, which is .1 ppm, to suggest that the amount of lead in these products was unsafe. *Id.*

No doubt as a result of this report, the FDA received numerous inquiries that led it in December 2007 “to allocate the resources necessary to conduct independent testing of a selection of lipstick on the market” and actually obtain “commercial samples of the same lipstick brands” identified in the Campaign for Safe Cosmetics Report. In June 2009, the FDA announced that its scientists had tested these lipsticks for total lead content and concluded “that the lead levels found are within the range that would be expected from lipsticks formulated with permitted color additives” and that it does “not consider the lead levels” that it “found in the lipsticks to be a safety concern.” Food and Drug Administration, *Lipstick and Lead: Questions and Answers* (Dec. 27, 2007, updated June 25, 2009, September 2, 2009, November 3, 2009, and December 5, 2011), available at www.fda.gov/oc/ohrt/lipstickandlead/

fda.gov/Cosmetics/productandingredientssafety/SelectedCosmeticIngredients/ucm128250.htm.

The FDA followed up with “an expanded survey of 400 lipsticks” purchased in the spring of 2010 and announced the results of that survey in December 2011. *Id.* This expanded survey found an “average lead concentration” that was “very close” to the average found in the initial survey, leading the agency to again conclude “that the amount of lead found in lipstick was very low and does not pose safety concerns.” *Id.* As might be expected and, as discussed below, a number of lawsuits were filed against various cosmetics manufacturers seeking relief for lead in lipstick.

Phthalates

Another group of ingredients used in cosmetics and beauty products that has received recent negative publicity is phthalates, a category of chemicals used in numerous personal care products such as nail polish, hair sprays, soaps, and shampoos. Center for Food Safety and Applied Nutrition, Food and Drug Administration, *Phthalates and Cosmetic Products* (Feb. 7, 2008), available at www.cfsan.fda.gov~dms/cos-phth.html. Unlike lead, which is generally acknowledged to be hazardous at certain levels, the actual health risk posed by phthalates is not clear. The CIR Expert Panel’s assessment is that the three phthalates used most in cosmetic products — dibutylphthalate (“DBP”), dimethylphthalate (“DMP”), and diethylphthalate (“DEP”) — “are safe as used in cosmetic products.” *Id.* The FDA itself says it “does not have compelling evidence that phthalates, as used in cosmetics, pose a safety risk.” *Id.*

Nonetheless, some phthalates have been banned in Europe, and there are an increasing number of reports of the potential health effects of these chemicals. *See, e.g.*, Natasha Singer, *Looking at the Bottle and What’s In It*, N.Y. Times, Feb. 15, 2007; J. Houlihan, et al., Environmental Working Group, *Not Too Pretty: Phthalates, Beauty Products & The FDA* (July 8, 2002) available at [\[toopretty_final.pdf\]\(#\). \(In another context, federal legislation banning six phthalates from children’s toys and other children’s products was enacted in August 2008, 15 U.S.C. §2057c, as was similar legislation in California and Washington State. Cal. Health & Safety Code §108937; Rev. Code Wash. §70.240.020. Several other states have considered doing the same.\) In the last several years, there have been several reports of links between phthalates and birth defects in boys, reproductive problems in men, and other health problems. Env’tl Working Group, Comments for Public Meeting, *supra*. Some phthalates are on California’s list of known carcinogens or reproductive toxins. If such general causation can be established, litigation claiming specific causation of injuries will certainly follow.](http://www.ewg.org/files/not-</p></div><div data-bbox=)

Dioxane And Other Chemicals

Another ingredient that has been the subject of consumer concerns is 1,4-dioxane, a chemical that has been shown to cause cancer in animals. Dioxane is not an actual ingredient in cosmetics or beauty products. Rather, 1,4-dioxane is formed during the manufacturing process. Food and Drug Administration, *1,4-Dioxane* (July 3, 2007), available at www.fda.gov/Cosmetics/ProductandIngredientSafety/PotentialContaminants/ucm101566.htm. In recent years, consumer groups have claimed to have found 1,4-dioxane in lotions, body washes, soaps, shampoos, and children’s bubble baths. Other chemicals that have received widespread attention for possibly causing negative health effects are the color additive para-phenylenediamine, found in certain black hennas, tuolene, which is used in nail polishes, and triclosan, an ingredient in anti-microbial cleansers. Food and Drug Administration, Warning Letter FLA-06-32 (Aug 14, 2006) (black henna), available at www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076032.htm.

Nanomaterials

One area in which there has been considerable activity and interest in recent years, and for which products liability litigation may be on the horizon, is the inclusion of nanomaterials in cosmetic and beauty products. Nanomaterials are generally defined as having at least one dimension of a size between one and 100 nanometers. *Draft Guidance for Industry: Safety of Nanomaterials in Cosmetic Products*, April 2012, available at www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ucm300886.htm. A nanometer is one-billionth of a meter. To compare, a human hair is 80,000 nanometers wide. Nanomaterials are “so small they can’t be seen with a regular microscope.” FDA Fact Sheet, *Nanotechnology*, April 2012, available at www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ucm300914.htm. Because of their size “nanomaterials can have different chemical, physical, or biological properties than their conventionally-scaled counterpart materials.” *Id.*

Starting in the late 1990s, manufacturers began including nanomaterials in various cosmetic and personal care products. *Beneath The Skin*, supra, at 12. The use of nanomaterials has grown exponentially in the last 10 years. As of March 2011, there were 1,317 products identified in the inventory of nanotechnology-based consumer products maintained by the Project On Emerging Nanotechnologies, a joint venture between the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts. Of these, 267 are personal care products, 143 are cosmetic products, and 33 are sunscreens. www.nanotechproject.org/inventories/consumer/analysis_draft/. Combined, the products in these three categories represent more than one-third of all products identified as containing nanomaterials.

The increased use of nanomaterials has been accompanied by increased concern about their possible effects on health and safety. See Note, *Not In My Makeup: The Need For Enhanced Premarket Regulatory Authority Over Cosmetics In Light Of Increased Usage Of Engineered Nanoparticles*, 26 J. Contemp. Health L. & Pol’y 82, 93-105 (summarizing research studies on effects of nanoparticles); see also *Beneath The Skin* supra, at 12-13 (“substantial evidence exists of real health impact concerns”). “Mineral sunscreens have attracted the most attention.” N. Singer, *New Products Bring Side Effect: Nanophobia*, New York Times, December 4, 2008. These products contain nanoparticles of zinc oxide and titanium oxide which some contend are toxic or have been shown to cause organ damage in lab animals. *Id.*; *Not In My Makeup*, supra, at 99 (“Nano-zinc oxide can result in tissue inflammation, production of ROS (reactive oxygen species) and lysosomal damage.”); see also *Beneath The Skin*, supra, at 13 (titanium dioxide in lungs “has proved to be toxic,” also discussing 2006 petition to FDA to regulate nanoparticle-containing sunscreen). Another category of cosmetics or personal care products that have come under scrutiny because of the inclusion of nanomaterials are anti-aging creams. Note, *The Dangers Of Chasing Youth: Regulating The Use Of Nanoparticles In Anti-Aging Products*, 2008 U. Ill. J.L. Tech. & Pol’y 199, 203-04. Others have identified purported risks from the use of nanomaterials because of their size and ability to enter the body easily through skin and lungs. *Id.* As might be expected, the increased use of nanomaterials has been accompanied by calls for regulation of these products. *Not In My Makeup*, supra, at 120. While the FDA has not undertaken any steps to regulate nanomaterials, in April 2012, it did issue the *Draft Guidance for Industry: Safety of Nanomaterials in Cosmetic Products*, supra, as part of its effort to describe “safety issues that manufacturers should consider to ensure that cosmetic products made with nanomaterials are safe and not adulterated.”

While no claims of injury arising from the use of nanomaterials have been made, at least one commentator has described the prospect of such claims as a “question ... not so much if, but when, nanotort claims and litigation will arise.” Ronald C. Wernette, *Nanoparticles: New Frontier For Mass-Tort, Class-Action Claims*, Commentary — 28 Westlaw Journal Toxic Torts 11 (Jan. 1, 2011).

PRODUCTS LIABILITY AND OTHER LITIGATION RELATED TO COSMETIC INGREDIENTS

• Unlike the rapid rise in litigation over various drugs and medical devices in the past decade, lawsuits claiming personal injuries as a result of the use of cosmetics or beauty products have been relatively few in number. Thus far, the litigation that has been filed specifically related to cosmetic and beauty product ingredients has been varied. As would be expected, traditional products liability claims have been asserted. Plaintiffs have sought compensation for injuries allegedly resulting from the use of certain products. In one case, the plaintiff claimed that the failure to warn of the need to perform a preliminary scalp test before using a hair texturizer was the cause of her contracting a staph infection. *Jack v. Alberto-Culver USA, Inc.*, 949 So. 2d 1256 (La. 2007). Another plaintiff, a user of talcum powder for decades, claimed to have contracted mesothelioma from long term use of the powder. See *Feinberg v. Colgate Palmolive Co.*, 2012 WL 954271 (N.Y. Sup. Ct. Mar. 22, 2012). In another case, the plaintiff claimed a number of injuries from failure to warn of the risk of an anaphylactic reaction to an ingredient in a hair dye. *Smallwood v. Clairol, Inc.*, 2005 U.S. Dist. LEXIS 2726 (S.D.N.Y. Feb. 18, 2005). Similarly, a purchaser of lipsticks that were identified as containing lead claimed injury from the use of the lipsticks. *Don's Frye v. L'Oreal USA Inc.*, 583 F. Supp. 2d 954 (N.D. Ill. 2008). In addition to consumers, individuals who work in industries that utilize beauty products have claimed occupational injuries. In one case, a hairdresser claimed

a variety of injuries from hair coloring products he claimed were defective because they contained harmful ingredients. *Coratti v. Wella Corp.*, 2006 WL 3718247 (N.Y. Sup. Ct. Dec. 15, 2006) (products liability action claiming multiple chemical sensitivity, inclusion body myositis, muscle disease, and chronic obstructive pulmonary disease from exposure to phenylenediamine and resorcinol in hair products).

“No Injury” Products Liability Claims

In addition to traditional products liability claims, some less-traditional legal strategies seeking to impose liability on manufacturers of certain cosmetic ingredients have been employed. Several of the recent lawsuits regarding lead in lipsticks have been filed as putative nationwide class actions. In many of these cases, plaintiffs have asserted what can be called “no injury” products liability claims. Plaintiffs do not claim to have suffered any injury as a result of exposure to lead through their use of the offending lipstick. Rather, they assert claims for medical monitoring to watch for potential future injuries, violations of consumer protection statutes, and breaches of warranties, among others. See, e.g., *Don's Frye*, supra; *Koronthalay v. L'Oreal USA, Inc.*, 2008 U.S. Dist. LEXIS 59024 (D.N.J. July 25, 2008), *aff'd*, 374 Fed. Appx. 257 (3d Cir. 2010); *Stella v. LVMH Perfumes & Cosmetics USA, Inc.*, 564 F. Supp.2d 833 (N.D. Ill. 2008). Similar claims have been asserted against manufacturers of baby shampoo and other products claiming fear of injury to children from methylene chloride, 1, 4-dioxane and formaldehyde. *James v. Johnson & Johnson Consumer Companies, Inc.*, 2011 U.S. Dist. LEXIS 5265 (D.N.J. Jan. 18, 2011); *Herrington v. Johnson & Johnson Consumer Companies, Inc.*, 2010 U.S. Dist. LEXIS 90505 (N.D. Cal. Sept. 1, 2010). Thus far, claims alleging economic or physical injuries arising from ingredients contained in cosmetics have not gained significant traction. The more traditional claims have been successfully challenged on the typical grounds —

lack of injury, lack of causation, or the provision of satisfactory warnings. *See, e.g., Don's Frye*, supra, 583 F. Supp. 2d at 958-59 (plaintiff's exposure to acceptable levels of lead not injury necessary for claim for medical monitoring); *Coratti*, supra, 41 Misc. 3d at 1204A ("Plaintiffs' theory of causation is not generally accepted within the relevant scientific and medical communities."); *Jack*, supra, 949 So. 2d at 1256 (warnings provided by the manufacturer "clearly" satisfactory). Lawsuits asserting less traditional claims have met with mixed results. Some have been dismissed for lack of standing. *Koronthaly*, supra. Others have survived at least the pleading stage. *Stella*, supra (denying motion to dismiss complaint).

Private Actions To Enforce State Health And Safety Requirements

A notable aspect of litigation related to ingredients in cosmetics is that claims have not been limited to the conventional consumer and products liability-type claims. Actions seeking to privately enforce state health and safety requirements are another vehicle by which consumers have sought to hold cosmetics manufacturers liable for inclusion of allegedly harmful ingredients in their products.

In California, under the Safe Drinking Water and Toxic Enforcement Act, commonly referred to as Proposition 65, anyone who "knowingly and intentionally" exposes others to chemicals "known to the state to cause cancer or reproductive toxicity" must provide a "clear and reasonable warning." Cal. Health & Safety Code §25249.6. What makes California's statute particularly powerful is if a warning is required but not provided, "any person in the public interest" may bring an action to recover a civil penalty of "\$2,500 per day for each violation" provided they have given written notice to the appropriate government authority and the alleged violator, and the governmental entity has declined to act. Cal. Health & Safety Code §25249.7(b), (d); *Baxter Healthcare Corp. v. Denton*, 15 Cal. Rptr. 3d 430

(Cal. Ct. App. 2004). There is an exception to the warning requirement for those chemicals where the manufacturer can show that exposure had "no observable effect assuming exposure at one thousand times the level in question" for items identified as reproductive toxicants or "no significant risk" for those identified as carcinogens. Cal. Health & Safety Code §25249.10(c). California maintains and publishes annually a list of chemicals "known to the state to cause cancer or reproductive toxicity." *Baxter*, supra, 15 Cal. Rptr. 3d at 434. Among the hundreds of chemicals currently on the list are 1,4-dioxane, lead, and the phthalate DBP.

Private actions seeking civil penalties for violations of Proposition 65 have been filed against a number of manufacturers in recent years. Claims have been asserted for an alleged failure to warn of the presence of lead in cosmetics, including lipstick. *See DiPirro v. J.C. Penney Co.*, No. 4017150 (S.F. Super. Ct. Feb. 9, 2005), in which the court concluded, after a 72-day trial, that neither J.C. Penney nor Macy's West had violated Proposition 65 by selling cosmetics that plaintiffs claimed contained lead. Indeed, in response to the attention to this issue, several manufacturers received notices of alleged Proposition 65 violations despite the fact the California Department of Justice has stated that "lead in lipstick ... up to 5 parts per million lead, does not raise a reasonable claim of a Proposition 65 violation and ought not to be pursued." Cal. DOJ Opinion Letter from E. Weil, Supervising Dep. Att'y Gen., to J. Slattery, D. Lavine.

Lawsuits have also been filed claiming manufacturers of nail polish have violated Proposition 65 by failing to warn consumers of the existence of the phthalate DBP in nail polishes. *Deubler v. Del Labs, Inc.*, No. BC 376033 (L.A. Super. Ct. filed Aug. 15, 2007). Manufacturers have also faced Proposition 65 actions brought by the California Attorney General for alleged failure to provide warnings of 1,4-dioxane in shampoos, body washes and gels.

People v. Avalon Natural Prods., Inc., No. RG08389960 (Alameda County Super. Ct. filed May 29, 2008).

ORGANIC AND OTHER CONTENT CLAIMS • Not only are cosmetics and beauty products being scrutinized for what they contain, they are being closely examined for how they are marketed. Two particular marketing strategies that have been the subject of recent litigation or may be areas soon to be litigated are the use of claims regarding the contents of cosmetics and beauty products and blending drug claims with cosmetic claims in the marketing of a particular cosmetic or beauty product.

The increased consumer attention to and interest in green products and products with a less harmful impact on the environment has spread to the cosmetic and beauty products market. The natural beauty market is one of the fastest growing segments of the overall personal care products market.

Definition Of “Organic”

Given the growing importance of natural and environmentally friendly products, the ability to use the description “organic” or designation that a product is certified “USDA Organic” can be highly valuable. Unfortunately, there is no uniformly accepted definition of an organic personal care product. A few countries have adopted standards under which cosmetics or beauty products may be certified as organic. There are also private standards. In 2005, the U.S. Department of Agriculture extended its National Organic Program, which governs foods and other agricultural products, to cosmetics. If a “cosmetic, body care product or personal care product contains or is made up of agricultural ingredients, and can meet” the requirements for certification under the U.S.D.A. standards, it may use one of the four organic labels available to agricultural products — 100 percent organic, organic

(which may be used if at least 95 percent of the ingredients are organic), made with organic ingredients, or identification of a specific ingredient as organic. 7 C.F.R. pt. 205; *see also* U.S.D.A. Agric. Mktg. Serv., Nat’l Organic Program, *Cosmetics, Body Care Products, and Personal Care Products* (Apr. 2008).

Generally speaking, to obtain the U.S.D.A. certification, a product must be made of farm products grown without synthetic fertilizers and pesticides, genetically engineered seeds, or irradiation. Due to these requirements, it is estimated that not many personal care products will qualify for U.S.D.A. certification. 7 C.F.R. pt. 205. It is no doubt for this reason that there has been litigation between trade groups claiming to certify or promote organic cosmetics, and natural cosmetic manufacturers over use of the term “organic” in connection with cosmetics. *See, e.g., All One God Faith, Inc. v. The Hain Celestial Group, Inc.*, 2009 U.S. Dist. LEXIS 115928 (N.D. Cal. dec. 14, 2009).

Definition Of “Cosmeceuticals”

As discussed above, the FD&CA defines a cosmetic as something “applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance.” In contrast, a drug is a product sold with or without a prescription, that is “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” or “intended to affect the structure or any function of the body. . . .” Given the two differing, but not mutually exclusive, definitions one product can easily be considered both a cosmetic and a drug. Antidandruff shampoo is an example given by the FDA of a product that meets the definition of both — a shampoo is a cosmetic because it is used to cleanse hair, and an antidandruff treatment is used to treat dandruff. FDA, *Is It a Cosmetic, a Drug, or Both?*, *supra*. Other examples of combined products are fluoride toothpaste and antiperspirant deodorants.

The term coined recently in the marketplace for products that have both cosmetic and drug attributes, though not a category of product recognized by the FDA, is “cosmeceutical.” This is another fast-growing market segment of the cosmetics market. One estimate is that sales of cosmeceuticals will approach \$12 billion in the United States by 2016. Abstract, *Cosmeceuticals In The U.S., 6th Edition*, Packaged Facts, April 2012.

Significantly, the FDA primarily determines whether a product is a cosmetic or a drug not from its content but from its intended use. *Estee Lauder, Inc. v. U.S. Food & Drug Admin.*, 727 F. Supp. 1, 2 (D.D.C. 1989). This use is, in turn, derived from “objective evidence such as the product’s current and past containers, instructions and advertisements.” *Id.* at 2. This approach has been criticized over the years as having created an “untenable system, in that the status of a product may change according to the whims of the manufacturer” and a “savvy manufacturer could keep its product from extensive regulation and premarket testing regardless of the product’s safety, merely by couching any advertising claims in vague, unverifiable language.” Laura A. Heymann, *The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids*, 52 Food & Drug L.J., 357, 365-66 (1997). As one commentator has pointed out “almost any cosmetic can be said to have some effect on the structure of the body.” *Id.* This same critic proposes a more practical definition of a cosmetic as a “substance that engenders a temporary superficial effect, linked closely to one’s appearance, while a drug ... causes a more permanent structural change in one’s health.” *Id.*

Consequences Of Marketing Cosmetics As Drugs

Because the distinction between a cosmetic and a drug is based primarily on intended use, how a product is promoted often determines whether it is considered one or the other or both. Claims that a skin care product “reduces redness,” or “smooth-

ens scaly skin” or has a “soothing, healing effect on dry, inflamed skin” have lead the FDA to classify the product as a drug. FDA, Warning Letter MIN-07-12 to BioForm Medical, Inc. (Feb. 15, 2007), available at www.fda.gov/foi/warning-letters/archive/g6265d.htm. This places a heavy burden on a cosmetic manufacturer as drugs are far more regulated than cosmetics. Most significantly, if a drug is also not generally recognized by qualified experts as safe and effective, it will be considered a new drug. *Estee Lauder, Inc. v. U.S. Food & Drug Admin.*, supra, 727 F. Supp. at 1, 2 (D.D.C. 1989). New drugs cannot be marketed unless a new drug application has been submitted and approved by the FDA. 21 U.S.C. §355 (a) and (b). The new drug approval process is extensive and requires research into a drug’s safety and efficacy, a full list of ingredients, and a description of the manufacturing process. *Id.*

Since at least the mid-1980s, when the FDA issued warning letters to 20 manufacturers and distributors of anti-aging or anti-wrinkle products, the FDA has monitored products that seek to bridge the cosmetic/drug divide. *Estee Lauder*, supra, 727 F. Supp. at 2-3. The FDA has paid particular attention to skin care products that are marketed with claims of acne treatment, cellulite reduction, stretch mark reduction, and wrinkle removal. *See* Center for Food Safety and Applied Nutrition, *Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics Page*, available at www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/WarningLetters/ucm081086.htm (page last updated April 21, 2011). The FDA considers these products drugs “because they are intended to affect the structure or function of the body.” FDA, Warning Letter to Hydroderm Beverly Hills (Sept. 26, 2005), available at www.fda.gov/ICECI/EnforcementActions/WarningLetters/2005/ucm075572.htm. Thus, it is obviously important for cosmetic manufacturers not

to convert their personal care products to drugs by means of unintentional marketing.

CONCLUSION • While not historically the subject of extensive litigation, cosmetic and beauty products are an area that may well see an increase in litigation activity in coming years. This may be true for no reason other than the tremendous in-

crease in the manufacture, sale, and purchase of cosmetic and beauty products. Moreover, the types of claims brought are increasingly likely not to be the traditional products liability claims with which litigators are familiar. Rather, litigation in this area is more likely to include claims of failure to disclose, and injuries from, unsafe ingredients or claims of improper marketing of personal care products.

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