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

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**Meryl C. Maneker** is a partner at Wilson Turner Kosmo, where her practice focuses on the defense of class actions as well as the areas of products liability, employment, and general business litigation. Her products liability practice focuses on the defense of manufacturers, distributors, and retailers of products. Her clients are corporations in a wide range of industries, including the manufacturers of automobiles and medical products. Her employment litigation practice focuses on the defense of employers in lawsuits involving claims of violation of wage and hour law, including class actions and other types of employment-related litigation.

**Vickie E. Turner** is a partner at Wilson Turner Kosmo. She has 30 years of experience in complex litigation matters filed against corporations, with extensive emphasis in the areas of products liability, warranty, and general business litigation. She has successfully defended manufacturers, distributors, and retailers in complex products liability claims throughout California, and in 12 other Western states. She was defense counsel for Ford Motor Company in a products liability case that was named one of the Top 20 Defense Counsel Verdicts for 2003. She also was selected as one of California’s Top Women Litigators in 2005 by the Los Angeles Daily Journal, and named one of San Diego’s top five products liability defense attorneys by San Diego Super Lawyers® in 2007, 2008, 2009, 2010, and 2011. She was also selected for inclusion in The Best Lawyers in America® 2010 and 2011 in the area of products liability, and named the Best Lawyers’ 2012 San Diego Product Liability Litigation — Defendants’ Lawyer of the Year. Ms. Turner has represented a wide array of companies in the defense of business disputes. Throughout her career, Ms. Turner has actively participated in lengthy mediations and arbitrations, as well as class action lawsuits.

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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, beautifying, 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 make-up 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&C Act 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(c).

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 Registration Program (“VCRP”). See Food and Drug Administration, Voluntary Cosmetic Registration Program (Nov. 15, 2012), available at [www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/default.htm](http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/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), (c) & (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 Envtl. 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