Regulatory Changes May Boost Cosmetics Liability Claims

By **Steven Napolitano**September 26, 2017, 11:27 AM EDT

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Cosmetics and beauty products are a massive, rapidly growing international industry. While cosmetic products are included within the ambit of the Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 301 et seq.), product liability counsel may not be aware that shampoos, face creams, lipsticks, makeup preparations and countless other products are subject to far less governmental oversight and control than food and drugs.

Because cosmetics and beauty products have traditionally been perceived as less dangerous to consumers, federal regulations have long treated these products with less scrutiny than other regulated products. Indeed, the original food and drug legislation enacted in the U.S. did not even include cosmetics products.

Despite this lesser scheme of regulatory control, there have been far fewer products liability claims concerning such products than seen in other areas of U.S. Food and Drug Administration oversight. Practitioners should be aware of growing support from industry, public health officials and elected officials to significantly alter the regulations governing cosmetic and beauty products.

High profile media reports of harmful cosmetic and personal care products and a perceived lack of FDA control over these products have seemingly permanently altered the public perception of the risks potentially posed by cosmetics. Legislation has been proposed this year in both the House and Senate that could significantly alter the regulation of cosmetics products to bring them more in line with other FDA regulated products.

While the likelihood of legislative reform in the 115th Congress is not clear, a number of the changes that have been proposed would almost certainly lead to increased product liability claims.

Senate and House Bills

The Personal Care Products Safety Act (S.1113) was first proposed in 2015 by Senators Dianne Feinstein, D-Calif., and Susan Collins, R-Maine. The Feinstein-Collins bill was reintroduced in the Senate in May of this year following changes to the earlier draft legislation.

This Senate bill is intended to protect consumers and create uniform safety rules over personal care products. Senator Feinstein commented in her press release of May 11, 2017, that "[d]espite the universal use of these products, none of their ingredients have been independently evaluated for safety," and that "we urgently need to update the nearly 80-year-old safety rules" governing cosmetic and beauty products.

In addition to protecting consumers, Senator Collins has stated that this proposed legislation would protect small businesses and provide regulatory certainty for manufacturers. On May 11, 2017, the Senate Bill was referred to the Committee on Health, Education, Labor, and Pensions.

The Cosmetic Modernization Amendments of 2017 bill (H.R. 575) was initially proposed by Rep. Pete Sessions, R-Texas, in November 2015. The 2015 Sessions bill was not voted on by the House and was reintroduced in January 2017. The stated goal of the House bill is to both protect consumers and to allow continued growth of smaller cosmetics companies.

The House bill, viewed by some as more "small business" friendly than the Senate alternative, has been referred to the House Committee of Energy and Commerce.

While the Senate and House bills diverge in some significant ways, and the Senate bill is generally more comprehensive, there are a number of provisions in both drafts that, if enacted, would significantly change how manufacturers do business in this area.

Adverse Event Reporting

The potential regulatory change that would most profoundly increase litigation risk in this area concerns the reporting of consumer adverse events.

As practitioners are likely aware, manufacturers of prescription drugs that receive reports of adverse events allegedly linked to one of their products are required to report that information to the FDA's Medwatch Program. Similarly, manufacturers of medical devices

are required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury.

However, manufacturers of cosmetics products have never had such mandatory reporting obligations under the FD&C Act. Commentators and watch groups have long contended that this system is flawed and leads to a vast underreporting of safety problems concerning cosmetic products.

Notably, both the Senate and House bills propose for mandatory manufacturer reporting of serious adverse events. The Senate bill would require companies to report “serious adverse events” associated with use of their products in the U.S. to the FDA within 15 business days, including death, “life-threatening experience,” inpatient hospitalization, persistent or significant disability, congenital anomaly or birth defect, or significant disfigurement.

Events that could have resulted in death, disfigurement or other reportable injury without early medical intervention would also have to be reported. The House bill likewise would require companies to notify the FDA within 15 business days of notice of a “serious and unexpected adverse event,” and includes a very similar definition of a reportable event as in the Senate bill.

It is important to keep in mind that in December 2016, the FDA announced that the Center for Food Safety and Applied Nutrition would begin posting on a quarterly basis data extracted from adverse event reports for cosmetics to improve transparency and provide greater access to government data.

In its Constituent Update of Dec. 6, 2016, the FDA stated that it “anticipates that this increased transparency will help spur the submission of more detailed reports from consumers, health care providers and other members of the public.” It is reasonable to expect that increased disclosure of cosmetic adverse event information will spur increased litigation regarding such products.

Enhanced FDA Testing of Cosmetics

As mentioned above, the FD&C Act relies on manufacturers to test their products and establish their safety. The FDA presently does not test or approve cosmetics before they can be sold. There is no FDA cosmetics pre-approval process other than the requirement

that color additives be FDA approved.

The Senate legislation proposed by Senators Feinstein and Collins would require the FDA to evaluate a minimum of five cosmetic product ingredients per year to determine their safety and appropriate use. The FDA would provide guidance on product use and labeling after such testing is concluded.

The Senate legislation would impose fees on cosmetics companies to help cover the cost of this FDA evaluation. The House bill does not include a similar provision to impose fees for FDA product ingredient testing, but would require manufacturers to file a cosmetic ingredient statement with the FDA for every product it sells.

Mandatory Recalls

The FDA does not have the authority under existing federal law to order a mandatory recall of cosmetics products. The FDA can only request that a firm recall a product, and can monitor recall effectiveness and issue its own press release announcing a recall if the company is otherwise unwilling to do so.

The Personal Care Products Safety Act would give the FDA the authority to order mandatory product recalls of personal care products if it determines there is a reasonable probability that the subject product is adulterated, misbranded or likely to cause serious adverse health consequences or death. A process is set forth for an informal hearing by the FDA prior to such an order.

Conversely, the House Cosmetics Modernization Amendments contain no such provision regarding mandatory recalls. As both practitioners and companies are likely well aware, a publicized product recall will almost inevitably be closely followed by adverse publicity and a spike in product liability claims.

Industry Support

There has been broad industry support for legislative change to address what many perceive as inadequate governmental control over the manufacture and distribution of cosmetic products. Industry support has largely broken down into two camps.

The House bill has been supported by Mary Kay, the Independent Cosmetics Manufacturers and Distributors, and International Fragrance Association, North America. The proposed Senate bill put forward by Senators Feinstein and Collins is supported by a broad array of the larger cosmetic and beauty products companies, including Estee Lauder, Johnson & Johnson, Procter & Gamble and Revlon, as well as the American Cancer Society and other nonprofit groups.

The leading national trade association representing the cosmetics industry, The Personal Care Products Council, has publicly supported regulatory reform to modernize the FDA's oversight of cosmetic products. The Council represents more than 600 member companies in the U.S. and internationally that manufacture and distribute cosmetics and personal care products.

On Jan. 18, 2017, president and CEO of the Personal Care Products Council Lezlee Westine released a statement supporting enactment of cosmetics reform legislation in the 115th Congress, stating that the Council and its member companies "reiterate our steadfast commitment to work with all stakeholders to modernize federal regulatory oversight for cosmetics and personal care products."

Among other things, the Council supports enactment of a "strong national program for the uniform regulation of all cosmetics in the United States" that preempts inconsistent state or local laws, a requirement that manufacturers "substantiate the safety of cosmetics products and ingredients," and mandatory reporting of serious and unexpected adverse health events.

Conclusion

While the Trump administration has been openly hostile to increasing federal regulation and bureaucracy, practitioners should carefully monitor developments in the area of cosmetics regulations. Broad industry support and increasing media scrutiny may spur cosmetic and beauty product regulatory reform that could directly affect product liability litigation in this area.

What precise form such reforms may eventually take remains uncertain. However, it is reasonable to assume the days of cosmetic products getting a "lighter touch" from the FDA may be drawing to a rapid close. If regulations are changed to move cosmetics more in line

with the rules governing food and drugs, it is quite likely that increases will be seen in the number of products liability claims concerning these products.

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