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Cosmetic Companies Must Plan For New Regulation

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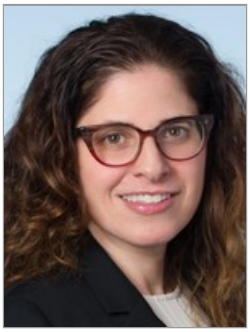

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Our mantra this year has been that cosmetic companies need to be prepared because change is on the horizon. Members in both parties of government have proposed cosmetic reform legislation, making it just a matter of time before Congress — likely with bipartisan support — makes significant changes to the way cosmetics and personal care products are regulated.

The Federal Food, Drug & Cosmetic Act (FD&C Act) defines cosmetics as "articles 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." Despite the fact that basically all people use some form of personal care product directly on their skin, the cosmetic industry in the United States has been largely unregulated when compared to drug, device and even food companies.

The U.S. Food and Drug Administration restricts cosmetic companies from making drug claims about their products, but with the exception of certain color additives, the FDA does not require preapproval of cosmetic or personal care products before companies can market their products in the U.S.

Under the FD&C Act, the sale of adulterated or misbranded products are, of course, prohibited, but that prohibition does not directly speak to the safety of the ingredients that go into the products. As a result, the companies themselves are currently responsible for validating the safety of their ingredients and finished products before bringing them to market.

Growing Support from All Sides for Greater Federal Regulatory Oversight

Signs suggest that both Democrats and Republicans on Capitol Hill are now ready to bring greater regulation to the personal care industry, which is a welcome change supported by the FDA, many industry members and various consumer protection groups. Indeed, most of the industry is in favor of the passage of a bill that will lead to greater regulation.

The cosmetic industry has received quite a lot of recent negative media coverage and been hit with lawsuits largely because of its lack of federal regulation of everyday consumer products, such as shampoos, moisturizers, nail polish, makeup, hair color and sunscreen. For example, the New York Times recently reported on the class-action lawsuit and settlement over WEN shampoos and conditioners, because the hair products were allegedly causing customers' hair to fall out. Similarly, Jessica Alba's Honest Company sunscreen recently faced bad press and class action lawsuits, because the sunscreen allegedly did not protect babies and children from sunburn.

The proposed amendments to the FD&C Act would put greater protections in place before products hit the market, thus taking away the uncertainty regarding safety that both consumers and cosmetic companies often face. Although the proposed statutory amendments may not rise to the level of regulation found in the more-heavily regulated medical device and pharmaceutical industries, at a

minimum, the cosmetic industry can expect to be more regulated than it has been over the last 80 years.

Two Competing Senate Bills Seek To Reform The Industry

In April 2015, Senator Dianne Feinstein, D-Calif., and Susan Collins, R-Maine, co-sponsored the Personal Care Products Safety Act, which they reintroduced in the Senate in May 2017. Recently, in October 2017, Senator Orrin Hatch, R-Utah, the most senior Republican senator, introduced the FDA Cosmetic Safety and Modernization Act. After Senator Hatch introduced his bill, Senator Feinstein stated that she "look[ed] forward to working with Senator Hatch to move this issue forward."

The senators' actions suggest that Congress will likely pass some form of cosmetic reform legislation, perhaps before the end of the current session in December 2018, which will result in greater scrutiny of cosmetics and personal care products. This, in turn, is likely to result in greater litigation against companies operating in these industries, similar to the significant litigation faced by the already heavily regulated food, pharmaceutical and medical device industries.

Both proposed bills would expand the FDA's oversight abilities in the cosmetic and personal care space in the following ways:

- They would require manufacturers and distributors to report to the FDA "serious adverse events" associated with the use of a cosmetic within 15 business days of receipt. Such reports are currently voluntary, and recent high-profile investigations of negative side effects from shampoos and other products, such as occurred with the WEN hair products, have starkly highlighted the current gap in the FDA oversight of this consumer product category.
- Although the competing bills diverge on the mechanism for reporting, they both would require the reporting of cosmetic ingredients and an assessment of their safety.
- They would require facilities to register with the FDA and would also provide the FDA with authority to suspend the registration of a facility whose products have a reasonable probability of causing serious adverse health consequences or death, as determined by the agency. Moreover, the Feinstein-Collins Bill would require the payment of a registration fee, which would be determined based on the company's annual gross sales of cosmetics.
- The FDA would be required to establish, and manufacturers would be required to comply with, good manufacturing practices. The Hatch Bill would give small businesses an additional year after the effective date of the legislation to comply with these standards.

The competing bills differ in certain respects. For example, the Hatch bill relies on congressional appropriations to fund the new work. In contrast, the Feinstein-Collins bill would allow the FDA to collect user fees from the industry, providing for an anticipated $20 million from the largest cosmetic manufacturers.

The Hatch bill also would give the FDA authority to accredit third parties to review and assess the safety of cosmetic ingredients and non-functional constituents. Such accredited third parties would have the authority to make recommendations to the FDA for proposed administrative orders. The Hatch bill does not set forth a timeline for these chemical safety reviews. In contrast, the Feinstein-Collins bill would require the FDA, not any third parties, to review the safety of five chemicals per year.

Furthermore, in general terms, the Feinstein-Collins bill would place the burden on manufacturers to show that chemicals used in cosmetic products pose a "reasonable certainty of no harm." The Hatch Bill, on the other hand, would place the burden on the FDA to show a cosmetic chemical is "not injurious" under customary or usual use.

Finally, and most importantly for determining the litigation impact of the two competing bills, the Feinstein-Collins bill gives the FDA authority to order mandatory recalls. The Hatch bill does not give the FDA any such authority.

It is worth nothing that the supporting constituencies for the competing Senate bills also differ in some respects. The Personal Care Products Council and Independent Cosmetic Manufacturers and

Distributors have expressed support for the Hatch bill. In contrast, supporters of the Feinstein-Collins bill include leading manufacturer Procter & Gamble and the Environmental Working Group (EWG).

In supporting the Feinstein-Collins bill, EWG articulated its view that the Hatch bill would not only be less protective of consumers, it would also fail to provide funding to the FDA to support its increased regulatory activities in the cosmetic space.

Companies Should Start Planning Now For Regulatory Changes

In light of the anticipated regulatory changes, companies in the cosmetic and personal care industry should consider implementing policies and procedures now to address the expected legislative reform. Because many of the proposed regulations have bipartisan support, companies can focus on those regulations to guide their preparation.

The requirement to record, track, investigate and report adverse event reports to the FDA will have the most profound impact on the industry. Manufacturers and distributors can prepare now for this legislation by implementing a system by which they internally record such reports, and carry out a thorough and well-documented investigation into the circumstances of the event and likely causes, including trending analyses.

Along those lines, companies can begin now to properly train their team to complete these reports in a manner that would not result in the reports being used in future litigation as admissions against the company. Having procedures in place for completing adverse event reports is especially important from a litigation perspective because product liability and consumer protection attorneys are notorious for mining adverse event databases looking for potential litigation.

Establishing procedures now to implement product-focused good manufacturing practices would also be beneficial for companies. If a company does not already have standard operating procedures in place, companies should start putting them in place and ensure that their SOPs include procedures for handling FDA inspections, corrective action plans and potential recalls (whether voluntary or mandated by the FDA).

Along the same lines, companies can begin creating policies and procedures now for the submission of ingredient information and the attestation of the safety of products. The content of the information shared, as well as the date when the information is shared, could become the focal point of litigation and raise potential preemption issues.

Accordingly, sharing the right information proactively, and receiving FDA guidance regarding product ingredients, can insulate companies from private litigation. Additionally, including appropriate warning labels on cosmetics now will enable companies to defend against future consumer claims related to a failure to warn users of a product's potential dangers.

New regulations are certain to lead to greater scrutiny, which in turn will most likely lead to a rise in the filing of product liability lawsuits, putative class actions and false advertising claims such as those brought under the California Consumer Legal Remedies Act. Companies should take the introduction of new industry regulations seriously and start planning now in order to be well positioned for when some version of the proposed cosmetic reform legislation become law.

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