

CLIENT ALERT

Bipartisan Bill Would Expand FDA's Reach Over "Personal Care Products" and Cosmetics

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In a rare show of bi-partisan cooperation, Senators Dianne Feinstein (D-Calif.) and Susan Collins (R-Maine) introduced a bill on Monday, April 20, 2015, that would expand the U.S. Food and Drug Administration's (FDA's) authority over cosmetic products sold in the United States. Titled the *Personal Care Products Safety Act*, the bill principally targets chemicals used in cosmetic products, with key provisions requiring manufacturers to register with FDA and report product ingredients. The bill would also require FDA to investigate the health hazards of five chemical ingredients each year, ban or restrict the use of certain hazardous chemicals, and grant the agency power to recall unsafe cosmetics.

Current Cosmetic Regulation and Proposed Changes

The scope of products impacted by this bill is enormous. Cosmetics are currently defined and regulated under the Federal Food, Drug, and Cosmetic Act (FDCA) 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." See FDCA § 201(i). This includes cleansing shampoos, permanent waves, and hair colors and also skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations and deodorants, as well as any substance intended for use as a component of a cosmetic product. Such products do not require FDA pre-market approval, and under current law, FDA has only limited enforcement options when such products are found to be adulterated, mislabeled or otherwise unsafe.

The proposed bill would significantly expand FDA's abilities and responsibilities regarding cosmetics under the FDCA. Specifically, the *Personal Care Products Safety Act* would:

- Provide FDA with authority to order recalls of certain cosmetics and personal care products that threaten consumer safety.
- Provide FDA with authority to require labeling of products that include ingredients not appropriate for children and those that should be professionally administered.
- Require complete label information, including ingredients and product warnings, to be posted online (approximately 40 percent of personal care products are currently purchased online).
- Require companies to provide contact information on their products for consumers and report serious adverse events to FDA within 15 days, including death, hospitalization and disfigurement. Health effects that could have resulted in hospitalization without early intervention would also be required to be reported.
- Require manufacturers to register annually with FDA and provide the agency with information on the ingredients used in their cosmetics and personal care products.
- Direct FDA to issue regulations on Good Manufacturing Practices for cosmetics and personal care products.

Additionally, it would require FDA to evaluate a minimum of five ingredients per year to determine their safety and appropriate use in cosmetics. The bill specifies the first set of chemicals to be reviewed and, while debate and negotiation may amend the list, those include:

- Diazolidinyl urea: a preservative used in deodorant, shampoo, conditioner, bubble bath and lotion
- Lead acetate: a color additive in hair dyes
- Formaldehyde/Methylene glycol: used in hair treatments
- Propyl paraben: a preservative used in shampoo, conditioner, and lotion
- Quaternium-15: a preservative used in shampoo, shaving cream, skin creams, and cleansers

Industry and NGO Support

As certain states, local municipalities, and at last count, over 20 national retailers including Whole Foods, Walmart and Target, have taken steps to restrict or ban certain chemicals in cosmetics, compliance has become complicated for the cosmetics industry. This bill would amend the FDCA to provide guidance and certainty to the industry and streamline federal standards regarding chemical content in personal care products. Industry appears to welcome that clarity. In responding to the bill's release, Personal Care Product Council President Lezlee Westine explained that "well-crafted, science-based reforms will enhance industry's ability to innovate and further strengthen consumer confidence in the products they trust and use every day. The current patchwork regulatory approach with varying state bills does not achieve this goal."

Accordingly, leading cosmetic and personal care manufacturers have publicly supported the bill. The Senate press release regarding the bill touted broad industry support, including from Johnson & Johnson, Procter & Gamble, Revlon, Estee Lauder, Unilever, L'Oreal, and the Personal Care Products Council. Notably, several consumer advocacy groups, including the Environmental Working Group, which has become known for its "Skin Deep" cosmetics ingredient database, are also supporting the bill.

Industry Costs and Future Planning

Implementing these proposed amendments to the FDCA is estimated to cost \$20.6 million annually. But the bill provides for these funds to be generated by new FDA-collected fees from cosmetics and personal care products manufacturers.

The bill still has a long way to go, but given the broad base of support the initial announcement seemed to enjoy, this legislation's prospects seem better than most in the current political climate. Interested parties should thus pay close attention as the bill winds its way through Congress, and manufacturers should examine now the potential impact that the bill's provisions might have on their products.

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