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PCPC 'Cautiously Optimistic' About Cosmetics Reform Bill Moving Through Senate

by Ryan Nelson

The Modernization of Cosmetics Regulation Act, part of must-pass FDA user-fee legislation, aligns with a number of the Personal Care Products Council's key principles for federal cosmetics reform. Preemption provisions could be stronger, but the bipartisan bill represents "a pivotal moment," the trade association says.

Legislation to modernize federal cosmetics regulations, part of a must-pass Food and Drug Administration user-fee bill moving through the US Senate, has the support of the Personal Care Products Council.

"From the outset of our advocacy around FDA cosmetics reform, our goal has been to work collaboratively with stakeholders to get a bill that would pass Congress with bipartisan support, one that could be implemented effectively by FDA," said PCPC's Karin Ross, executive vice president, government affairs, in a 16 June interview.

The Modernization of Cosmetics Regulation Act (MoCRA) included in the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022, introduced on 26 May by Sens. Patty Murray, D-WA, and Richard Burr, R-NC, could mean that PCPC's goal is achieved.

"We have worked on numerous iterations of federal cosmetics reform over the past 10+ years," Ross said. "As is the nature of any legislation, we had to work hard with other stakeholders to find an appropriate landing spot, and as part of this process we understand that FDA staff also have been engaged heavily with the Senate HELP Committee."

She continued, "We are hopeful that this effort results in a new federal framework that

strengthens FDA's regulatory authority, reassures consumers about the safety of their personal care products, and allows the beauty industry to continue to make safe and innovative products that consumers demand."

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PCPC's *principles* for federal cosmetics reform include mandatory registration of manufacturing facilities, product/ingredient reporting to the FDA, serious adverse event reporting, and establishment of cosmetic good manufacturing practices, all of which MoCRA would put in place.

PCPC also supports granting FDA the authority to access company records and/or order cosmetic product recalls when it has a reasonable belief that a product could cause serious adverse health consequences. MoCRA would do that as well, and it would require by statute that all cosmetics manufacturers substantiate the safety of their products, again lining up with PCPC's stated principles.

The bill, which the Senate Health, Education, Labor and Pensions Committee voted to advance to the full Senate on 14 June, includes preemption terms as well. Preemption, aka "national uniformity," appears at the top of PCPC's principles.

However, the preemption sought by PCPC would bar "state and local laws for all cosmetic ingredients based on human health concerns if the FDA has reviewed the ingredient's safety or has been presented with a safety review of the ingredient by the Expert Panel for Cosmetic Ingredient Safety and, after a period for the FDA review, has not rejected the Expert Panel's safety finding."

MoCRA makes no mention of Cosmetic Ingredient Review's Expert Panel for Cosmetic Ingredient Safety, and in fact expressly provides that states could continue to prohibit or restrict use of ingredients in cosmetic products.

Ross noted, "While we are pleased to see explicit, express preemption in the bill, PCPC and our member companies believe the preemption provision could be strengthened to provide clear uniformity that advances safety, innovation and consumer confidence. We have provided input to the Senate HELP Committee and look forward to continuing our work with Congress on this

issue."

PCPC also supports the creation of an FDA program for reviewing the safety of cosmetic ingredients and nonfunctional constituents, which is absent from MoCRA.

Nevertheless, "PCPC believes the new cosmetic safety provisions … will help FDA ensure the safety of cosmetics and personal care products and their ingredients, and provide FDA with a host of tools and resources to oversee the industry," Ross said.

'A Pivotal Moment'

Counterpart legislation in the House, which passed on 8 June, does not include MoCRA. Energy and Commerce Committee chair Frank Pallone, D-NJ – who introduced legislation in the previous Congress to modernize federal cosmetics oversight, which did include FDA ingredient review – has suggested that reconciling House and Senate versions of the FDA user-fee bill should pose no significant challenges. (Also see "*US Bill To Radically Overhaul Cosmetics Regulations Passes Senate HELP Committee*" - HBW Insight, 14 Jun, 2022.)

That process will take place in July.

Burr, who coauthored FDASLA, voted against the bill as amended in Senate HELP's 14 June markup. In a same-day statement, he says, "The amendments that were added during today's markup take us backwards, making it more difficult to bring life-saving products, treatments, and cures to Americans. That goes against the entire purpose of this bill."

The Independent Beauty Association is still forming its position on MoCRA. PCPC, which says almost half of its members qualify as small and medium-sized enterprises, supports the bill's inclusion of special provisions for small businesses, including giving them flexibility and additional time to comply.

Whereas the Personal Care Products Safety Act, S. 2100, and previous bills for cosmetics reform have included registration fees to fund FDA activities, MoCRA would do so through congressional appropriations, from $14.2m for fiscal year 2023 to almost $42m for each of fiscal years 2025 through 2027.

Ross concluded, "The Senate HELP Committee's bipartisan introduction of MoCRA represents a pivotal moment in the multi-year effort around cosmetics reform. PCPC stands ready to continue to work with Congress, members of the HELP Committee and key stakeholders to build on the substantial progress made to date. We remain cautiously optimistic."