Rose Sheet

Pharma intelligence | informa

Your complimentary Rose Sheet content

Rose Sheet
Pharma intelligence | informa

ICMAD Looks To Sway Legislators To Sessions Cosmetics Bill

By Lauren Nardella

WITH LETTERS TO KEY LEGISLATORS IN the House and Senate, the Independent Cosmetic Manufacturers and Distributors looks to build support for the approach laid out in the Cosmetics Modernization Act of 2015, maintaining that the front-running Personal Care Products Safety Act is a danger to small business.

• • •

The Personal Care Products Safety Act, S. 1014, and its companion proposal in the House would hamstring the small business sector and ultimately could be a disservice to consumers, according to Pam Busiek, president and CEO of the Independent Cosmetic Manufacturers and Distributors.

"The price of excessive regulation, regulation that exceeds that which is required to ensure safe products that perform well, could well put many of our members out of business, leaving the market dominated by the larger multinationals, who would then be in control of the product pricing," she asserts in an Oct. 14 letter to New Jersey Reps. Frank Pallone, D, and Leonard Lance, R.

A similar letter went out the same day letter to Sen. Lamar Alexander, R-Tenn, chair of the Senate Health, Education, Labor and Pensions Committee. In both letters, she seeks to turn the congressmen's focus to the alternative cosmetics reform bill currently in play – the Cosmetics Modernization Act of 2015, H.R. 4975 – which has been seen as less of a contender to date.

Like the PCPSA, the CMA, sponsored by Rep. Pete Sessions, R-Texas, would give FDA greater insight into the cosmetics industry and product safety issues through mandatory facility registration, product/ingredient statements and adverse-event reporting requirements.

However, the CMA would not establish a framework for FDA to systematically review cosmetic ingredients like that provided by the PCPSA; instead, it would approve a potentially vast number of ingredients as safe for use in personal-care products based on their approved safety status in other contexts.

> **"The Feinstein/Collins approach to the standard for safety substantiation and documentation far exceeds those applied to dietary supplements, which unlike cosmetics have a significant record of serious adverse events," Busiek says.**

In contrast to the PCPSA, the CMA also would not require FDA to establish through rulemaking Cosmetic Good Manufacturing Practices, authorize the agency to order product recalls or provide user-fee funding to support FDA's increased oversight activities.

Moreover, the bill's preemption provisions would go well beyond the PCPSA by barring states from establishing or continuing virtually any cosmetics regulations. (Also see "House Cosmetics Bill Seeks Broad Federal Preemption, Revised 'Cosmetic' Definition" - Rose Sheet, 22 Nov, 2015.)

ICMAD maintains that legislation ensuring national uniformity is essential to the health of small business. In her letter to Alexander, she says ICMAD members do not have the staffing to navigate the growing number of state

regulations and may have to stop selling in states that impose additional regulatory requirements on companies.

"This puts them at a competitive disadvantage versus some of the bigger companies in the industry," she says. "We need to relieve this burden and not add to it," she asserts in the Pallone/Lance letter.

According to the exec, it would be "incongruous" to enhance FDA's authority while allowing states to continue statutes that undermine that authority, and the approach could lead to state courts making determinations regarding federal matters."

She points to the single, uniform standard established for cosmetics regulation in the EU, arguing that there is little reason a similar approach can't be taken in the US.

Busiek said in a September interview that ICMAD planned to continue work informing legislators about the need for reasonably expanded federal oversight in lieu of the growing patchwork of state regulations facing industry at present. (Also see "ICMAD: Small Business Looks To Pull Off Preemption Balancing Act" - Rose Sheet, 26 Sep, 2016.)

During a Senate Health, Education, Labor and Pensions Committee hearing exploring cosmetics safety, ICMAD and the Personal Care Products Council affirmed their support for a strong national standard (Also see "Industry Makes Pitch For National Uniformity At Senate HELP Hearing" - Rose Sheet, 26 Sep, 2016.)

Busiek also takes issue with the revenue threshold for registration fee exemption in both the Pallone/Lance discussion draft and the PCPSA, which is set at $500,000.

The $500,000 figure is "not a realistic test for what constitutes a small business," she says, characterizing the amount as "significantly off the mark." In a competitive industry such as cosmetics, a company would not be able to survive at such a low revenue level, according to Busiek.

The exec goes on to question the fairness of the fee schedule. "By setting the revenue test so low, and with the percentage contribution required by the lower-level-revenue companies, the smaller companies will pay a disproportionate share of the user fees and a greater percentage of fees on a per-dollar-of-revenue basis than the multinationals," she says.

The Handcrafted Soap and Cosmetics Guild similarly feels the $500,000 threshold is too low. (Also see "Handcrafted Cosmetics Sector Says Exemptions In Reform Bills Are Insufficient" - Rose Sheet, 5 Oct, 2016.)

Busiek stresses cosmetic products' strong safety record compared with other FDA-regulated areas, which is evidenced by insurance ratings.

"Our cosmetic products enjoy far lower premiums than any of these other categories, as there are very few incidents of injury, even minor injuries, with regard to cosmetics than with other regulated classes of products," she says.

She suggests that under the PCPSA and House discussion draft, cosmetics would be held to more stringent adverse event reporting requirements, lower standards for enforcement actions and generally a higher bar for safety than dietary supplements and monographed OTC drugs, which pose significantly greater risks.

"The Feinstein/Collins approach to the standard for safety substantiation and documentation far exceeds those applied to dietary supplements, which unlike cosmetics have a significant record of serious adverse events," Busiek says.

By reaching out to HELP Committee Chair Alexander, ICMAD could get the attention of a lawmaker wary of FDA's overextension. During the September hearing, the senator noted concern about putting more on the agency's already full plate. (Also see "Sen. Alexander Questions FDA's Slow Response To WEN Complaints" - Rose Sheet, 28 Sep, 2016.)

In her letter to the New Jersey congressmen, Busiek points out that many of ICMAD's member companies call the Garden State home.

PCPSA 'Well-Intentioned' But Oppressive

Busiek thanks Alexander for convening the recent hearing on cosmetics safety and for allowing ICMAD member Jack Black LLC to testify.

While the hearing did not focus on the details of the PCPSA, in her letter Busiek argues that PCPSA "is well-intentioned, [but] would ultimately do more harm than good in the name of promoting safety."

Considering the impact PCPSA would have on small businesses, she urges Alexander to consider the Sessions bill as a viable alternative.

ICMAD says its plan for modernizing FDA oversight, as framed by the CMA of 2015, would be more appropriately scaled and would build on requirements that have been successful in other FDA programs.

"By utilizing and enhancing systems and facilities that are currently in place at the FDA, the burden on the FDA and industry alike will be minimized in adopting and complying with these enhanced requirements," Busiek says.

From the exec's perspective, the CMA would help to clear market entry barriers and burdens that could stifle innovation.

She says the bill would provide for adverse event reporting in a way that would be consistent with what's already required by the OTC drug monograph system, compared with the PCPSA, which not only requires reporting of serious adverse events within 15 business days of receipt, but also an annual report of all adverse events communicated to companies.

She concludes by emphasizing again that there is little sense in pushing for a strong FDA without providing authority for a strong national standard.

"We know it is not every day that you hear an industry group pressing for a national standard, but if done correctly, we know that this will strengthen consumer protections while fostering the innovation and entrepreneurial spirit that defines the cosmetic industry."