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Making Cosmetics Reform Beneficial For All; Former FDA Cosmetics Director Yearns For 'Serious Sit-Down'

by Eileen Francis

Federal legislative reform is an historic opportunity not only to strengthen the US FDA's oversight of the cosmetics sector, but also to modernize the industry and its value proposition to consumers. John Bailey, independent advisor for cosmetics and colors at EAS Consulting Group, is confident there's a way to do all, but "serious" stakeholder negotiations are needed.

Industry veteran John Bailey, who served a decade as director of the US Food and Drug Administration's Office of Cosmetics and Colors, is confident there is a way to meaningfully update federal cosmetics regulations to benefit all stakeholders.

The Senate's current proposal in the FDA Safety and Landmark Advancements (FDASLA) Act, *S. 4348*, is not it, he says.

"I would love to have a serious sit-down in negotiations with the people who are writing this bill and to make it a good, beneficial bill for the industry, both large and small, for consumers, and for the US as a competitive market," said Bailey, independent advisor for colors and cosmetics at EAS Consulting Group, in an 8 June interview with HBW Insight.

As introduced, S. 4348 was "clearly not written by somebody [representing] the best interests of cosmetics businesses in the US, especially the small businesses," he said.

Bailey has ideas for moving the US industry forward, with an eye on elements of the EU system. He noted, "Europe allows certain limited structure function claims. I think cosmetics are safe in Europe. They could be just as safe in the US but allow companies to state the effects that their products are demonstrated to have, the benefits of these products, to consumers."

He also believes some restructuring at the FDA could be warranted. “The location of the cosmetic program is very problematic. It doesn't fit well in any center. In drugs, it would get lost in the more impactful, health-wise, nature of drugs. Drugs need to be focused on COVID, cancer cures, and all the other wonderful things they do. They would have no interest in cosmetics.”

However, Bailey suggested, it could be beneficial to move at least some OTC drugs – sunscreens, antiperspirants, dandruff shampoos and the like – into the cosmetics regulatory structure.

“The so-called non-dose-limited OTC drugs are regulated as cosmetics in Europe, and they function just fine. Maybe the thing to do is to establish an office or center for cosmetics and over-the-counter drugs,” he said, while acknowledging the move would pose significant infrastructure and cost challenges.

In any event, the FDA’s cosmetics unit “needs to have enough autonomy to be able to do the things that are necessary for the cosmetics industry and consumers of cosmetics without being a low priority in drugs or oddball in the center for foods,” Bailey said.

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Legislative reform is an opportunity to evolve the cosmetics industry and pave the way for a bright future. But the proposed FDASLA leans in a direction that is more about “command and control,” according to Bailey, who also served previously as executive vice president for science at the Personal Care Products Council.

“I think the NGOs have really undue influence, and that shows in this bill. We've worked hard to provide input, and we end up with provisions that are just dealbreakers in my mind,” he said.

FDASLA, which would reauthorize drug, medical device and other user fee programs at the agency, also would beef up the FDA’s cosmetics oversight authorities and create significant new requirements and costs for cosmetics manufacturers in line with other legislative reform proposals past and present, including the Personal Care Products Safety Act, S. 2100.

The Senate Health, Education, Labor and Pensions Committee, which circulated a discussion draft of the bill before it was introduced on 26 May by Sen. Patty Murray, D-WA, plans to take a closer look at S. 4348 in an executive session on 14 June. (Also see "*Senate HELP Floats Draft For*

US Cosmetics Reform; Top Trade Groups Hustle To Respond" - HBW Insight, 19 May, 2022.)

"Because this is part of the user free re-authorization with drugs, if there's any headwind that occurs for acceptance or modification of the cosmetics part of it, it will not pass, is my thought," Bailey said, adding, "And it shouldn't pass as it currently is written."

According to Bailey, there are changes that could be made to the bill to make it more palatable.

He said industry largely supports proposed requirements for cosmetics facility registration and product/ingredient listing, which currently occurs only through the FDA's Voluntary Cosmetic Registration Program. The agency reported in May that the VCRP has garnered more than 4,000 active cosmetic establishment registrations and almost 27,000 product filings since it moved to an online system in September 2018.

First created in 1972, the VCRP regularly provides data to Cosmetic Ingredient Review, where Linda Katz, director of the FDA's cosmetics office, acts as a liaison to the group's independent expert panel. CIR's future is uncertain under various legislative proposals for cosmetics reform, particularly bills that would task the FDA with systematically reviewing ingredients. FDASLA omits any mention of such a program.

Bailey has been an advocate for continued utilization of CIR and its extensive body of ingredient safety data. He noted that making VCRP essentially a mandatory program would strengthen data that inform CIR prioritization and safety assessment work.

It also would improve the FDA's understanding of the industry and marketplace. "A mandatory program allows a better hand on the pulse of changes in the industry regarding ingredients that are used. I think that's a reasonable thing," he said.

Less Reasonable Things

Bailey is less on board with some of the additional powers the FDA would be granted by FDASLA. (Also see "*Cosmetics Industry Stakeholders Not Thrilled About Senate Reform Bill, And Why Should They Be?*" - HBW Insight, 9 Jun, 2022.)

"Where it falls down is that this gives the agency the authority to suspend the registration of a facility," he said. "If the condition of manufacturing and marketing requires registration of product, the FDA could suspend that – basically shut a company down – and that could happen by just a bureaucrat in Washington in the Office of Cosmetics and Colors saying, 'We don't like what you're doing.'"

Bailey also takes issue with the bill's proposal for FDA to establish by regulation good manufacturing practices for the cosmetics industry. A proposed regulation would be due no later

than two years after enactment and a final version one year later. Currently, cosmetics industry GMPs are laid out in June 2013 draft guidance from the agency.

“It’s not a dealbreaker for me, but it’s a serious flaw,” Bailey said. “For the cosmetics industry, it’s not necessary to have a GMP regulation because it’s such a heterogenous industry.”

Bailey continued, “It’s many small and large-scale companies making a vast array of products that have different functions, compositions. And to write a GMP is going to be very difficult, especially a regulatory GMP because regulations are so hard to promulgate and so hard to update,” he said.

GMPs should remain in the form of guidance, Bailey said. “Guidance is much easier to keep up to date, and I know that from my time with FDA.”

Bailey also is concerned that violations of GMP regulations could lead to unnecessary shutdowns of cosmetics business, as happens with drugs. “Of all the products regulated by FDA, cosmetics are by far the safest. So you really don’t have the need to apply such draconian approach for cosmetics.”

In Bailey’s view, FDASLA’s section on cosmetics safety substantiation also needs rethinking. The bill would require companies to appoint a responsible person to ensure, and maintain records supporting, that cosmetic products are safe, meaning neither they nor their ingredients are “injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.”

Minor and transient reactions or minor and transient skin irritations in some users would not constitute an injurious finding under the bill.

Adequate substantiation would be defined as “tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.”

Bailey said while there is general consensus that cosmetics should be substantiated for safety, the legislation still lacks a clear “metric” for the purpose. “There needs to be some reference to apply that. It can’t just be safe as determined by somebody sitting in an office and saying, ‘Well, we think that’s unsafe.’”

He also zeroed in on language suggesting that the FDA could consider “cumulative or other relevant exposure to the cosmetic product, including any ingredient thereof,” as part of a safety determination.

The notion of taking cumulative exposure into account is “very problematic,” he said. “In the safety world, the toxicology world, measuring cumulative exposure and safety is practically impossible, especially for a cosmetic company, and [more so] for a small cosmetic company,” he said.

Further, the issue of cumulative exposure does not only apply to cosmetics. “It applies to all products FDA regulates,” Bailey noted, adding, “There needs to be a more robust and balanced approach to that.”

Fragrance Concerns

Bailey has concerns about provisions related to fragrance ingredients as well. FDASLA would authorize the FDA to ask a responsible person for a complete list of fragrance ingredients in a cosmetic product if the agency has reason to believe fragrance is the cause of a reported serious adverse event.

He noted that due to supply chain complexities and trade secret protections, such information is not always available to cosmetic product manufacturers.

Consumer advocacy groups including Breast Cancer Prevention Partners and Women’s Voices for the Earth are pushing for even stronger provisions for fragrance ingredient disclosure that would make the information publicly available. ([#ARS152565])

FDASLA also would require the FDA to develop by regulation a list of fragrance allergens that must be identified on cosmetic product labeling, similar to requirements in the European Union. Bailey expressed reservations about the specifics of that piece, while noting, “FDA has the authority to look at allergens in general, and certainly fragrance allergens are something that are of concern.” (Also see "*US FDA Support For Cosmetic Allergen Labeling Has Foundation In Consumers' ‘Right To Know’*" - HBW Insight, 28 Oct, 2021.)

New Problems, And Same Old Ones

Perhaps most importantly, FDASLA would not address some of the biggest challenges cosmetics businesses face in the US, including the ever-growing patchwork of state and local requirements that companies are forced to navigate.

In fact, the bill’s preemption section expressly preserves state and local governments’ right to restrict ingredients as they see fit. The bill also includes a savings clause to ensure that liability suits against cosmetic companies could go on uninterrupted.

Recent decisions by federal courts, including in California, have strengthened cosmetics industry confidence in federal preemption defenses, specifically in cases alleging the unlawful sale of unapproved drugs masquerading as cosmetics. (Also see "*Plaintiff Claims Against Beiersdorf For*

'Unlawfully Marketed Drug' Are Preempted By FDCA, Court Rules" - HBW Insight, 24 Apr, 2020.)

Despite some optimistic developments, the carnage continues. (Also see "*Prostaglandin Analogues In Eyelash Cosmetics: Rodan & Fields To Settle Litigation For $38M*" - HBW Insight, 30 Mar, 2022.)

"The litigious nature of what's going on right now with the plaintiffs' attorneys somehow needs to be put into context," Bailey said. "We're seeing more and more of it, and to whatever extent that can be reined in and made more difficult for plaintiffs' attorneys to go after companies for things that are really not a problem" would go a long way to improving the health of the industry, he suggested.

Ultimately, such factors bear on US competitiveness. The US cosmetics sector is "kind of losing ground, especially to Europe," Bailey said. "We have a very innovative and creative cosmetics sector, small businesses, doing wonderful things. I like to think that most of your new small businesses are women-owned businesses. And that's great, we should encourage that, not discourage it."

The Independent Beauty Association also has highlighted the large number of female- and minority-owned cosmetics businesses on the rise and the jobs the industry creates for those demographics, which could be threatened by disproportionately burdensome cosmetics regulations. (Also see "*Cosmetics Sector Needs Positive, Not Punitive, 21st Century Regulation – IBA*" - HBW Insight, 17 Feb, 2021.)

According to PCPC, women make up 77% of the cosmetics and personal care industry's workforce and hold more than half of management positions, and people of color account for 33% of the workforce.