

US GOVERNMENT SHUTDOWN IMPERILS REFORM HOPES

HAPPY New Year! A new US Congress has been sworn in and, at press time, it is facing major political challenges over the border wall and ensuing federal government shutdown. Guess what will also suffer? The OTC Reform Act. As of Jan. 8, 2019, both the House and the Senate were working on finalizing the Reform Act. Late that evening, the House of Representatives passed legislation (HR 269) that would modify the FDA's process for regulating OTC drugs, including new and pending sunscreen ingredients, by a vote of 401 to 17. The bill will now be considered by the Senate.

Disagreements in the Senate during the previous session had stalled progress on the legislation, thus putting the future of the Act in doubt in the new Congress. Other pending legislation relating to the nationwide banning of oxybenzone and octinoxate, sponsored by Senator Jeff Merkley (D-OR) and Representative Tulsi Gabbard (D-HI), is obviously on hold, too. Meanwhile, Hawaii and the nations of Palau and Bonaire went ahead with



At press time, Democrats and Republicans remain this far apart on border security; an argument that led to US federal government shutdown and imperiling critical sunscreen legislation.

their bans of oxybenzone and octinoxate, and legislation to ban both ingredients is pending in California; Key West, FL; and North Queensland, Australia.

On January 15, the Key West City Council voted 7-0 to approve the measure. A final vote is scheduled for February 5. If legislation is passed in Key West, where the UV Index is the highest in the US, it would be particularly troubling, as it includes a proposal to require a medical prescription for individuals who wish to use products containing octinoxate and/or oxybenzone. This is a serious development since it usurps the authority of the FDA to legislate sunscreens; it is a dangerous precedent in sunscreen regulations.

Dire Warnings

For all who have read my columns for the past few years, you know that I am not a fan of oxybenzone. However, requiring a prescription to use a product will dampen all efforts for the liberal use of sunscreens for protection.

Most US sunscreen manufacturers are heeding the warnings that oxybenzone and octinoxate may soon be banned nationwide. They are busy reformulating the 70% of products on the US market that contain these two ingredients in anticipation that they may be banned. The buzzwords in the industry today are "Hawaii-compliant" and many raw material suppliers are presenting data and formulations of sunscreens without oxybenzone and octinoxate. DSM, a major ingredient supplier to the sunscreen industry, showcased its Hawaii-compliant formulations during In-Cosmetics North America in October.¹ Most formulations feature all-mineral sunscreens which are not only very expensive for the mass market but are also inherently difficult to formulate and yield less elegant formulations with limited shelf life at the initially-designed SPF.

I'm repeating myself, but with only seven potentially approved filters in the US, it is practically impossible to produce



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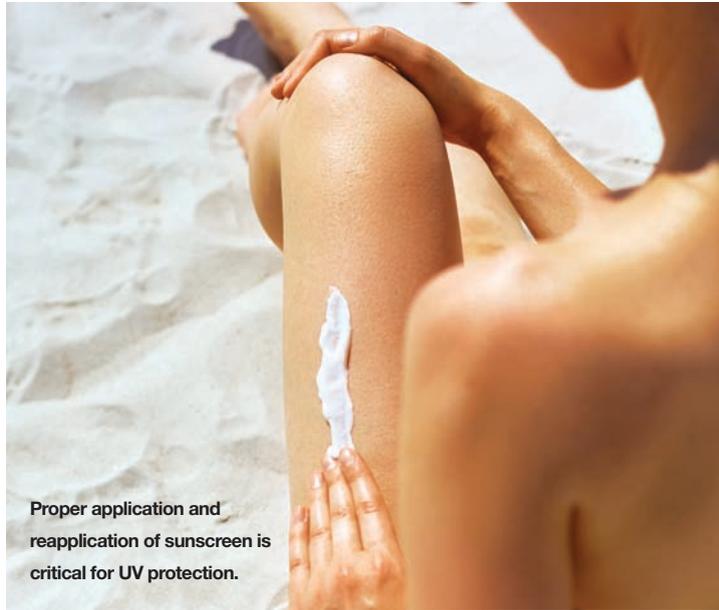
effective UVA broad spectrum protection at an affordable price. Without new UV filters or the already globally-approved TEA ingredients, it will be a monumental task to undertake.

Where is Congress? Where is the FDA? Where are the advocacy groups, including the Personal Care Products Council, on securing new effective filters? Where is the American Medical Association, the American Cancer Society, the American Academy of Dermatology, the Skin Cancer Foundation and myriad skin care advocacy groups? It's high time that the industry, and all those affected organizations, toss their hats into the ring and focus—really focus—on the real issue of adequate protection facing our industry and our society.

Predictions made all over the internet by industry market analysis companies celebrate the possibility that the global market for sunscreens will have a compound annual growth rate of 5.8% to reach \$25 billion by 2024.² If correct, that is a phenomenal incentive for cosmetic and sunscreen manufacturers and entrepreneurs. But I must ask: what kind of products will be produced by them and what kind of protection will these products provide? Will a \$25 billion industry provide incentives for entrepreneurs to produce products that encourage people to use sunscreens that eliminate, or significantly reduce, the incidence of skin cancer? I hope so, but if we have only seven UV filters to accomplish this formidable task, I seriously doubt that it will happen.

Some Good News

Encouraging new studies are being conducted in our field, but these studies are getting side-tracked by the politically-charged climate and stalled legislation. Take, for example, an Australian study in the *Journal of Investigative Dermatology*, which reported that ZnO nanoparticles



do not penetrate skin.³ The study showed that ZnO nanoparticles dissociated into zinc ions and that the nanoparticles did not enter the skin intact. This study provides the first evidence that intact ZnO nanoparticles neither penetrate the human skin barrier nor cause cellular toxicity after repeated application.

Another study at the University of Maryland School of Pharmacy revealed that the hot sun actually increases the skin absorption of UV filters, in particular oxybenzone.⁴ During a cancer conference in Glasgow, Scotland, Dorothy Yang reported that skin cancer deaths are on the rise for men living in developed nations around the globe and that men have a higher rate of skin cancer deaths than women.⁵

During a National Melanoma Summit in Auckland, Davis Whitman from the QIMR Berghofer Medical Research Institute in Brisbane, Australia reported that Kiwis in their 20s and 30s have lower melanoma rates than their parent's generation.⁶ Elsewhere, Stephanie Blake from the University of South Wales, reported that sunscreen use does not affect vitamin D levels in individuals exposed to the sun.⁷ An Olay study at Harvard Medical School reported on genes contributing to skin cancer⁸ and a Kings College (London) study suggested that

typical use of sunscreens offers less sun protection.⁹ All of these studies and many more in the literature are a reminder that controversy in protection still exists and extensive additional research needs to be done to solve those issues.

I am a scientist and not a politician. Every time I write my column, I find numerous articles and developments in our industry that I long to report. Instead, political developments that impact regulations—or lack of regulations—in our industry leave me flabbergasted. My attentions turn to Congress, the FDA, and, this month, the border wall with Mexico and the government shutdown. I do so because I am cognizant of the shortcomings in our industry and our dismal efforts toward producing new effective sunscreen products that would eliminate or significantly reduce skin cancer rates, the most prevalent cancer in the US! ●

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