

# RECENT DEVELOPMENTS IN SUNSCREENS

**M**Y PREVIOUS column announced that the US Food and Drug Administration would issue its Final Guidance on Sunscreens in late November. Indeed, FDA did! Regulators detailed the data that manufacturers of sunscreens sold over the counter need to supply to prove that the ingredients in their products are safe and effective. The FDA has not approved a single Time and Extent Application (TEA) ingredient that are pending for dozens of years now. Instead, FDA has added many new impediments for the approval of new sunscreens for the US market.

The FDA is moving full-speed-ahead with treating sunscreens as drugs; expecting the full complement of drug tests that any cancer or medical ailment-curing-pharmaceutical drug requires. This includes human dermal safety studies (human irritation and sensitization studies and human photostability studies) and new human absorption studies (Maximum Usage Test; aka, MUsT) along with added pediatric considerations. On the non-clinical safety testing, they require



FDA has floated the idea of *invitro* permeation testing of sunscreen formulations.

both dermal and systemic carcinogenicity studies, developmental and reproductive toxicity studies, and toxicokinetics. The FDA has also added post-marketing safety data requiring that manufacturers provide a myriad of information on adverse drug experiences and reported side effects.<sup>1</sup>

In my previous columns, I wrote extensively on the new MUsT test, that determines whether the sunscreen ingredient is absorbed into the blood and to what degree it is absorbed. In our meeting with the FDA in November, the Public Access to Sunscreen (PASS) Coalition produced an extensive document by Edward Sargent and Jeffrey Travers that was a peer-reviewed publication in *Regulatory Toxicology and Pharmacology*,<sup>2</sup> which noted that this test has never been conducted on any sunscreen product to date, that no protocols were developed or validated for sunscreens, and that the standard of 0.5 nanogram/ml (equivalent to an exposure of 0.5 ppb steady state level) is an arbitrary standard. The publication has suggested a paradigm for non-clinical safety testing of sunscreens, a rational

pathway by which UV filters can be safely tested to introduce new protection products to the US market. Unfortunately, the late November 2016 FDA Guidance for Industry did not consider any of our suggestions or protocols.

A potentially more serious proposal that the FDA has floated in this guideline—one that would be an impediment to speedy introduction of sunscreens by manufacturers—is the testing of the final formulations before going to market. The FDA has requested that all manufacturers perform *invitro* permeation testing before marketing any new formulations. This brand-new requirement will have a major impact on our industry if implemented. Manufacturers should rise, debate the issue and contact the FDA about its ramifications.

Unfortunately, the whole issue of regulations can be significantly improved if the US has better ultraviolet filters that are similar to those broad-spectrum UVA/UVB filters in Europe and if we remove the low molecular weight UVB filters that we currently have in the US. This discussion



**Nadim Shaath**  
*Alpha Research  
& Development Ltd*  
Email: [alphamd@aol.com](mailto:alphamd@aol.com)

Dr. Nadim Shaath is the president of Alpha Research & Development, Ltd. in White Plains, NY. He has over 30 years of experience as chairman of the chemistry department at SUNY-Purchase and the CEO of Kato Worldwide. Recently he formed a consulting company serving the cosmetic industry called ShaathMeadows Corporation (SMC) with laboratories in New York, New Jersey, Texas, Florida and Egypt.

is decades old, yet nothing has been done about it so far. In a recent report by Dr. Steve Wang and associates, they report that about half of the US sunscreen products do not meet European standards of UVA protection<sup>3</sup>. In the meantime, skin cancer rates keep soaring!

Meanwhile, Congressman Dr. Tom Price has been appointed Secretary of Health and Human Services. At press time, the current nominee to lead the FDA is Dr. Scott Gottlieb. Regardless of who is serving in the Trump Administration, the Affordable Care Act (Obamacare) will dominate the discussions and the Sunscreen Innovation Act will take a back seat.

The only glimmer of hope is that Senator Johnny Isaacson, our champion in the Senate, is friendly with Dr. Price who served with him on the Georgia Congressional delegation, and perhaps he may be influential in taking our message to him.

## Rays of Hope

Every column that I write lately has been addressing the lack of adequate US regulations, and I always try to incorporate the positive developments in our industry. Unfortunately, studies that are conducted/published are few and far in between, and they usually emanate from academia and medical/dermatological institutions. Manufacturers are obviously discouraged from introducing new filters as the current state of regulations effectively bars them from reaping any commercial gains. Nevertheless, there are a few recently-published studies.

A new Northwestern Medicine study published in the Journal of JAMA Dermatology found that consumers are confused by sunscreen terminology; only 43% understood the definition of SPF. Seven percent knew what to look for on

a label for products that offer protection against early skin aging! The study surveyed 114 participants who attended the Northwestern Medicine Dermatology clinic and was conducted during the summer of 2014.<sup>4</sup>

In a recent editorial in the Journal of Clinical Oncology, Tamar Nijsten, PhD, at the Erasmus Medical Center in Rotterdam, The Netherlands, wrote that the long-term effects for sunscreen non-users may be significantly different from sunscreen users. He outlined the factors that affect outcomes when comparing the relationship between sunscreen use and melanoma

eco-system.”

Should the bill pass, the ban would take effect in early 2018, making Hawaii the first state to ban sunscreens with oxybenzone. We will be on the lookout to see if other states plan similar legislation.<sup>6</sup>

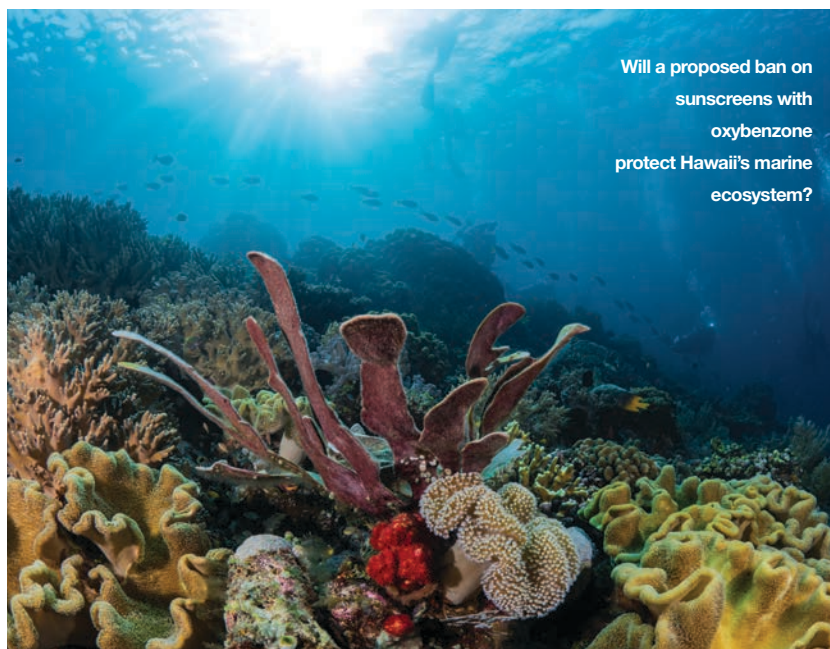
Peyman Derikvand and his colleagues published a paper in the European Journal of Phycology suggesting that sunscreens and moisturizers derived from biological sources such as cyanobacteria could represent a safer alternative to our current synthetic ultraviolet filters. Cyanobacteria, a blue-green algae with species that live in arid habitats, produce mycosporine-like

amino acids (MAAs) and a molecule called scytonemin, which provide effective protection from long- and shortwave UV radiation, respectively. Unfortunately, once again, very interesting basic research in producing natural ingredients to replace our synthetic UV filters, may go down the drain unless the FDA has a miraculous change of heart.<sup>7</sup>

In conclusion, the lack of clear, definitive regulations

in the US is contributing significantly to the chaos that is prevalent in the sunscreen industry. Serious impediments to the introduction of new potent and effective broad spectrum ultraviolet filters is discouraging basic research by industry and academia that could produce potentially new molecules that are capable of providing the proper protection from the debilitating sunrays.

Lastly, I would like to apologize for the several-month delay in writing The Sunscreen Filter. I was busy with my new book, “Healing Civilizations: The Search for Therapeutic Essential Oils and Nutrients,” which was published



Will a proposed ban on sunscreens with oxybenzone protect Hawaii's marine ecosystem?

development, and found that outcomes are tied to skin pigmentation differences and how users apply sunscreen. Nijsten pointed out that higher socioeconomic status may play a role in the development of skin cancer with sunbathing vacations and the use of indoor tanning. Other factors he pointed out included how often individuals apply sunscreen and reapply water-resistant sunscreens after sweating and swimming.<sup>5</sup>

Hawaii State Senator Will Espero plans to introduce a bill that would ban sunscreens containing oxybenzone. Senator Espero stated that “a ban is the right thing to do in order to protect our fragile marine

by Cameron Books, Petaluma, CA and released in January 2017. This book is the culmination of my personal journey around the world during the past 25 years, seeking out and rediscovering essential oils and therapeutic ingredients that have been in use since antiquity. It's also a reference manual with technical data for practitioners in the field of aromatherapy, essential oils and perfumery, and is a guide for those interested in natural healing. (For a review of *Healing Civilizations*, see "An Essential Read," p. 46, *Happi*, March 2017.) ●

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