

SOME POSITIVE DEVELOPMENTS IN THE SUN CARE INDUSTRY

IN MY previous column (August 2016, p. 36) we played the blame game in the sunscreen industry. I highlighted many of the negative developments in the industry and who was responsible for this perceived deterioration in the protection of our consumers from the ravaging rays of the sun.

Now, let's look at the other side of the coin. In this column, I will attempt to outline the positive developments in sun care and conclude with where we are heading in sunlight protection protocols.

Solar radiation (including ultraviolet and infrared) is an environmental carcinogen that can cause melanoma and non-melanoma skin cancers when individuals are exposed to it. It is estimated that 3.5 million cancers are diagnosed in about 2.2 million patients in the US. It is reported that 95% of the ultraviolet radiation reaching the keratinocytes and melanocytes are UVA rays. Thus, protection from the UVA rays in particular is crucial in the prevention of both melanoma and non-melanoma skin cancers.

Unfortunately, UVA filters in the US,



Despite many issues, there are some bright spots in the sun protection saga.

in particular, require substantial improvement. The inorganic filters, ZnO and TiO₂, offer reasonable protection from the UVA, but their formulations are generally not cosmetically appealing and tend to break down more readily than formulations with the traditional chemical absorbing filters. Two such absorbing filters are approved in the US, namely oxybenzone and avobenzone. The former has been implicated in endocrine disrupting action, and the latter has photostability issues requiring quenching with other filters and special formulation techniques. In contrast, the rest of the world has access to many effective UVA filters that have been in use for more than a decade.

As most of you know, several groups in this industry joined hands and established the PASS (Public Access to Safe Sunscreens) coalition that lobbied Congress to address the lack of adequate sunscreen protection for the American consumer. In November 2014, the US Congress unanimously passed legislation called the Sunscreen Innovation Act (SIA),

which President Barack Obama immediately signed into law. The SIA requires the FDA to complete a review of the Time and Extent Application (TEA) that have been pending approval for more than a decade and determine the safety and efficacy of those sunscreen actives within 300 days or less. Unfortunately, the FDA promptly rejected all eight pending applications and required extensive additional safety data. These included systemic carcinogenicity studies, systemic reproduction and development toxicity studies, and animal toxicokinetics—after repeated application and human topical safety studies!^{1,2} In addition, the FDA recommended further human pharmacokinetic data under maximal use conditions to evaluate dermal penetration of the UV filter in order to make a GRASE (Generally Regarded As Safe and Effective) determination. This new test was termed MUsT (Maximal Usage Trial).

It should be noted that the MUsT study has never been conducted on any sunscreen product, nor any protocols developed or validated for sunscreens with



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an arbitrary standard of 0.5 nano gram/ml (equivalent to an exposure of 0.5 ppb steady state level in the blood).

A Positive Development

The PASS Coalition responded by commissioning a study by Edward Sargent (Rutgers University) and Jeffrey Travers (Wright State University) who recently published their findings in *Regulatory Toxicology and Pharmacology* (2015).³ This exceptional 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 sun protection products to the US market.

The PASS Coalition has since requested a meeting with the FDA to discuss this proposal. FDA is now contemplating a public forum to be scheduled soon to evaluate the MUsT test protocol and other relevant issues in sun protection. Perhaps this proposed public meeting, if held, can be considered a positive development in sunscreens!

More Good News

Other positive developments have been the recent studies addressing photoprotection with sunscreens. These studies include the Australian study by Green and coworkers who demonstrated

efficacy in melanoma prevention by using broad-spectrum sunscreens and long-term monitoring.⁴ Also, Ghiasvand and colleagues from the University of Oslo in Norway, published a paper in the *Journal of Clinical Oncology* demonstrating that the use of sunscreens with an SPF of 15 or greater was associated with about a 30% reduction in the risk of melanoma among huge populations (143,844) of Norwegian women aged 40 to 75.⁵

Also, researchers from the University of Bath in the UK have developed a chemical compound that claims to offer unprecedented level of protection against the harmful effects of UV radiation. This compound called the "mitoiron claw" is capable of protecting the mitochondria where the concentration of free iron is particularly high.⁶ Researchers exposed human skin cells to the equivalent of 140 minutes of sun exposure at sea level. The cells that were treated with the mitoiron claw were protected whereas those that were not treated with that compound did not survive. Obviously, this is an important development, but given the current backlog at the FDA, it may take many years, if not decades, to approve new filters for sun protection.

No significant development in sun care and photoprotection is imminently possible in the current environment of regulations at the FDA. Treating sunscreens as drugs, as opposed to cosmetics in a manner similar to the majority of regulations in other



Europeans have access to better sunscreens.

countries, is an insurmountable barrier that will delay the introduction of better protocols of protection. Until then, it is prudent that all methods of sun protection including sun avoidance during the hours of 10am to 3pm where possible, along with the usual protocols of applying an adequate amount of broad spectrum SPF 30 or higher sunscreen before sun exposure, reapplying every two hours and using proper clothing, umbrellas and hats. Routine examination by a dermatologist is also highly recommended to reduce the complications of over exposure to the sun. Pray also for a change of heart at the FDA! ●

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