

SPOTTY DEVELOPMENTS IN SUN CARE

MY APOLOGIES for not writing my column in April as I was busy with completing my new book on essential oils and aromatherapy ingredients. The manuscript entitled "Healing Civilizations: The Search for Therapeutic Essential Oils and Nutrients" is now with my publisher Cameron Books and will be released in January 2017.

Recent developments in the field of sunscreens have been spotty and disappointing. It has been 18 months since President Obama signed the Sunscreen Innovation Act (SIA) into law. Since then, the FDA has been stonewalling any progress to move any of the Time and Extent Application (TEA) ingredients forward and closer to approval in the US.

In April, the American Academy of Dermatology (AAD) held a two-hour focus session in Washington DC that was attended by Terry Michelle from the FDA.¹ She argued that the sunscreen products of today are used in a manner that is quite different from the way they were envisioned to be used back in 1978. Today, sunscreens are used on a daily basis

throughout the year—not just for a few times a year on family vacations. No additional safety requirements were added for the current approved filters, and as a result no new UV filters will be further approved without scrutiny and additional testing.

In previous columns I alluded to the MUSt (maximum use test) and other in vitro tests that the FDA is proposing to demonstrate the safety of UV filters and their degree of permeation into the skin. This protocol remains as an untested proposal. This 30-day test was developed by the FDA to evaluate the potential for systematic



New FDA commissioner
Robert Califf

drug absorption at the upper limit of use covered by the clinical trials and allowed for in the label. The MUSt trial must demonstrate a de minimus rate of absorption of no greater than 0.5 ng/ml. It should be pointed out that the MUSt test has never been tested on any sunscreen ingredient, and the threshold limit suggested was arbitrarily set.²

Now that Dr. Robert Califf has been approved by the Senate as the FDA commissioner, there is a glimmer of hope that some movement on the SIA is imminent. The PASS Coalition met with Califf and his senior advisors including Dr. Janet Woodcock, Terry Michelle and others on May 6. The meeting was very positive and Dr. Califf was supportive of the PASS Coalition's efforts, but he stressed that the FDA with the scientific case addressing the safety and efficacy of new ingredients including additional testing protocols that is satisfactory for all.

Once again, the ball is in our court to

make the case for new ingredients.

Moonshots & Long Shots

Last year President Obama appointed Vice President Joseph Biden to head the National Cancer Moonshot effort, and last month Greg Simon was appointed executive director to the White House Cancer Moonshot Task Force. Greg Simon served as Vice President Al Gore's top domestic advisor in the 1990s, and we plan to meet with him soon to deliver our concerns regarding the Sunscreen Innovation Act and the need for additional measures to combat skin cancer.

On March 21, 2016, a group of 70 public health deans at institutions of higher education sent a letter to Vice President Biden urging him to place a strong emphasis on public health and prevention noting that "the cancer moonshot must incorporate the best available tools. Our goal in the ensuing decades should be to eliminate cancer mortality. Clearly, a cancer cure is a laudable approach to that goal, but it is also possible to imagine a world where many types of cancer, like polio and rabies, will simply no longer occur."³ Investments in public health and cancer prevention can make an enormous impact on reducing cancer incidence and mortality and should be a priority of the Cancer Moonshot initiative.

Edited by Dr. Steven Wang and Dr. Henry Lim, a new book on sunscreens has been published by Springer International. It includes contributions from top scientists and dermatologists in the field. The book, a welcome addition to practitioners in the field of sunscreens, is entitled "Principles and Practice of Photo Protection." Its publication comes 11 years after my own book called "Sunscreens" was published by Taylor and Francis in 2005 and eight years after Henry Lim and Zoe Draelos' book, "Clinical Guide to Sunscreens and Photoprotection."



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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.

A sun care workshop was held at In-Cosmetics Europe in Paris. It featured prominent scientists in the field of ultraviolet filters and sunscreens. Dissemination of information is vital at this stage in the development of cures for skin cancer and improved products to combat the disease.

May was Melanoma Awareness month; having crucial information to the public is imperative. Other activities are planned. On May 27, the National Council on Skin Cancer Prevention planned to hold a "Don't Fry Day," and on June 14, the AAD is holding a Congressional skin cancer screening.

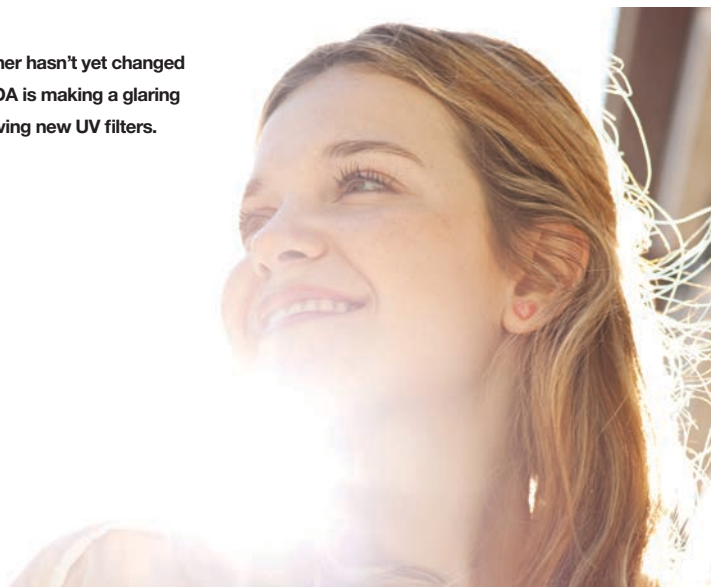
A new study by Dr. Niels Skakkeback and colleagues from the University of Copenhagen in Denmark was presented at the Endocrine Society Conference. It reported that some of the UV filters used in the sun care industry may be disrupting the normal function of sperm cells through "induced calcium ion fluxes." Since these chemicals might contribute to unexplained male infertility, Dr. Skakkeback concluded "regulatory agencies should have a closer look at the effects of UV filters on fertility before approval."⁴ Of course, after the presentation was reported in the press, social media outlets had a field day warning all males to be concerned about infertility and weakened sperm counts if they use sunscreen products for protection from the harmful rays of the sun.

Some Good News

On a positive note, Dr. Christin Burd, a molecular genetics professor from Ohio State University, conducted an experiment to determine the effectiveness of sunscreens in preventing the development of skin cancer. Results were presented at the annual meeting of the American Association for Cancer Research (AACR) in New Orleans in April where Burd and her colleagues described how they produced genetically engineered mice to test the efficacy of sunscreen products in preventing sunburns and melanomas.⁵

The researchers exposed the mice to a single dose of UV light a day after administering the chemical agent 4-hydroxytamoxifen (4OHT), which induces

A new commissioner hasn't yet changed the fact that the FDA is making a glaring error by not approving new UV filters.



melanoma in the genetically altered mice. They found that the animals developed melanoma and tumors at a much faster rate as compared to those that were not exposed to UV light. However, when the mice were given an SPF 30 sunscreen that contained UV filters, the occurrence of melanoma and the development of tumors were reduced significantly. Unfortunately, not all sunscreens tested provided the same degree of protection despite being labeled as SPF 30. This finding is quite significant and must be expanded to determine the exact nature of the UV protection required to significantly reduce the risk of contracting melanoma.

On the regulatory front, the Federal Trade Commission (FTC) finally intervened to stop excessive claims of "all-natural" or "100% natural" brands made by Trans-India Products (Shikai), Erickson Marketing Group (Rocky Mountain Sunscreens), ABS Consumer Products (EDEN body works) and Beyond Coastal Sunscreens. A fifth company, California Naturel, is still facing an FTC complaint (see Regulations, p 30 in this issue). In another development, a Neutrogena class-action lawsuit was dismissed in March in the US District Court for the Southern District of Florida since the plaintiff in the case could not recollect basic information about the product when questioned on the stand.⁷ The judge found the plaintiff could

not establish that he had been harmed and that the lawsuit lacked the requirement of "typicality" (the plaintiff's injury could not be typical of other members of the proposed class).

With summer just around the corner, we are again reminded of the importance of protecting ourselves, and those we love, from the known risks of the sun's damaging rays. Enjoy the summer fun and the summer sun, but always use sunscreens despite their current shortcoming, along with adequate clothing protection. ●

References:

1. 74th American Academy of Dermatology (AAD) Annual Meeting, Walter E. Washington Convention Center, Washington D.C. March 4-8, 2016.
2. Happi, The Sunscreen Filter, Nadim A. Shaath, p. 41-43, November 2015.
3. Letter to Vice President Biden on March 21, 2016 from the Association of Schools and Programs of Public Health (ASPPH)
4. N. Skakkeback, et al., presentation at the annual Endocrine Society Conference, Boston, Massachusetts, April, 1-4, 2016
5. Christin Burd, Et al., presentation to the American Association for Cancer Research (AACR), New Orleans, April 2016.
6. <http://www.lexology.com/library> April 20, 2016.
7. <http://www.legalnewsline.com/stories> April 29, 2016.