

NO DEARTH OF PLAYERS FOR THE BLAME GAME

Finger pointing is a favorite activity of the self-righteous.



THIS COLUMN will tackle the problems with sun care protection in general. My next column will address the solutions for better sun care protection.

Fifty years ago our sunscreen industry began to grow. In 1966, the consumer demanded protection from the UVB rays. A tan was considered healthy and offered

a glow to the face that reflected prosperity and younger-looking skin. Today we have an epidemic rise of skin cancer with over two million new cases annually in the US, countless deaths from melanoma, mistrust regarding the effectiveness of sun care products and only 3% of women who say that a deep dark tan is attractive. Scathing conflicting reports, articles, and blogs appear each day that lambast the effectiveness and safety of sun care products in the US.

The most outrageous statement made recently to several Congressional staff on Capitol Hill came from Dr. Theresa Michele, director, Division of Non Prescription Drug Products (DNPD). She insisted that not everyone can get skin cancer from the sun, but everyone can get skin cancer from sunscreens! Michelle is in charge of overseeing sunscreen regulations at the FDA and her statement, if true, reflects the sentiments and attitudes toward new and improved sunscreen ingredients and regulations. God help us!

The Environmental Working Group (EWG) issued its 10th annual report in May with headlines such as "Sunscreen Should Be Your Last Resort." EWG rates sunscreens

on the market mostly based on very limited criteria, reporting that few sunscreens meet this criteria.¹ According to EWG, all of the mass marketed sunscreens, which are used by more than 80% of the US public, are ineffective and should be avoided. Any sunscreens that contain oxybenzone (benzophenone-3) or retinyl palmitate (vitamin A) or have an SPF above 50 are given a low rating or deemed unsafe. Their criteria are centered on using inorganic particulates (non-nanoparticles) and avoiding any of the workhorse chemical UV absorbers.

About the same time, Consumer Reports (CR) issued a scathing report on US sun care product testing entitled "Your Burning Questions, Answered."² After testing 65 lotions, creams and stick sunscreens, CR editors found that nearly half of them (43%) had SPF values well below their label SPF. In fact, one SPF 50 product tested at 8! It should be noted, however, that Consumer Reports uses an alternative test to the FDA monograph approved protocol to measure SPF.

In another new report published online by JAMA Dermatology, researchers at Northwestern University School of Medicine in Chicago analyzed 65 sunscreen products (1% of the 6,500 sunscreen products on the market) and found that 40% of the most highly rated sunscreens did not adhere to AAD guidelines, primarily due to their lack of actual resistance to water and sweat. The researchers also cautioned against the misuse of claims such as "safe for sensitive skin," "preservative free" or "non-comedogenic."³

Social media lights up with negative reporting too, adding to the utter confusion for the consumer who seeks protection from the sun's ravaging rays. In the past few months, incendiary headlines that appeared include "Sunscreen Doesn't Work as Well as They Say: What to Do?"⁴, "Excuse Me While I Lather My Child in this Toxic Death Cream"⁵, "Sunscreens Destroy Coral Reefs"⁶, "Sunscreens Disrupt Sperm Cell



Nadim Shaath
Alpha Research & Development Ltd
Email: 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.

Function”⁷ and so on. When you combine these doom and gloom articles with reports by the US Food and Drug Administration in its “Ingredient Assessment Guidance”⁸ arguing that sunscreen ingredients “fall short,” it is no wonder why we have a crisis in our arsenal for solar protection in the US.

Of course, there are a few positive developments in sun care and solar protection including the efforts of the Public Access to Sunscreen (PASS) coalition which led to the enactment of the Sunscreen Innovation Act (SIA).

Also the White House Cancer Moonshot Task Force, spearheaded by Vice President Joe Biden, is a clear step in the right direction. Elsewhere, a Ohio State University study revealed that as much as 80% of melanoma cases can be avoided with SPF 30.⁹ Finally, the efforts of the Skin Cancer Foundation, the Melanoma foundations and programs including Melanoma Monday and the May Skin Cancer Awareness Month and the free sunscreens distributed in Miami, Boston and other city beaches, should all be applauded. These programs, unfortunately, are barely making a dent in our efforts to reduce the incidence of skin cancer and to protect the consumer from the damaging rays of the sun.

Blame Game

This month’s column is about the “blame game” and there is plenty of it to go around. The FDA has abdicated its role in approving superior sunscreen ingredients that have been proven effective in Europe and the rest of the world. At an event for the White House Cancer Moonshot Task Force on June 29, Vice President Biden remarked, “I might add parenthetically, there’s been no real progress in sunscreen, in new sunscreen application, in, I don’t know for a fact, but almost two decades. That’s a long time.”¹⁰

The consumer shares the blame by not heeding advice to avoid the harsh sun between 11am and 4pm, for not wearing protective clothing, for frequenting tanning salons; and, most importantly, for failing to properly apply adequate amounts of sunscreens. A recent report appearing in the JAMA declared that only 14.3% of men use sunscreens regularly, and countless reports show that the average consumer is grossly under applying sunscreens before exposure. The sunscreen manufacturers share the blame by not sponsoring basic research in securing superior sunscreen actives, by not studying the underlying causes of contracting skin cancers, and by not aggressively promoting superior protocols of protection. Undoubtedly, the barriers set up by regulatory agencies reduce the incentive for expensive research, but the effort must be increased dramatically to reduce the alarming skin cancer statistics worldwide.

One final comment needs to be made about the FDA’s response to the Sunscreen Innovation Act of November 26, 2014. On May 23, 2016 the FDA sent to Congress its report signed by the new Commissioner, Dr. Robert Califf (addressed to the Honorable Fred Upton, chairman of the Committee on Energy and Commerce at the House of Representatives), covering the 18-month period from November 26, 2014 through May 11, 2016.¹¹ I will only cite the conclusion section of the FDA report here:

“Conclusion: [The] FDA has met all of its statutory obligations



Games that people (and the institutions they create) play.

under the SIA to date. [The] FDA is committed to doing its part to provide American consumers with additional options for safe and effective sunscreen active ingredients. [The] FDA met promptly with sponsors to discuss sunscreen data requirements and provided relevant draft guidance to assist sponsors. [The] FDA relies on industry to

submit the additional data needed to support a determination that a sunscreen containing a given active ingredient would be generally recognized as safe and effective.”

My only comment here is that since August 2002 (14 years ago), not a single Time and Extent Application (TEA) ultraviolet filter was approved in the US. In fact, since 1978 (38 years ago) only two UV filters, avobenzone and zinc oxide, have been approved in the US. I am cognizant of the fact that sunscreens are not the only mode of protection and regimen for reducing the incidence of skin cancer worldwide, but sunscreen products emanating from new and advanced basic research of superior UVA protection are not being formulated today in US products.

My next column will address the modest procedures and protocols for improving solar protection worldwide. I welcome your input and suggestions on the topic in the next few weeks to make my recommendations

more meaningful. Send your comments to Alpharnd@aol.com. ●

References:

1. 10th Annual Guide to Sunscreens, www.ewg.org/sunscreen
2. “Your Burning Questions, Answered,” www.consumerreports.org, July 2016.
3. www.inquisitr.com July 08, 2016.
4. Linda Johnson, AP Medical writer, Associated Press, July 1, 2016 <http://abcnews.go.com/health>
5. www.collective-evolution.com/2016/06/12
6. www.honolulu.magazine.com/June 2016.
7. www.huffingtonpost.com/2014/05/12/sperm-cells-endocrine-disruptor-chemicals_n_5310784.html
8. chemicalwatch.com/45498/US-FDA-Sunscreens-ingredients-guidance-falls-short
9. Christin Burd, et al, Presentation to the American Association for Cancer Research (AACR), New Orleans, April 2016.
10. www.c-span.org/video/?c4608389/miami-beach-sunscreen-program
11. www.fda.gov/downloads/drugs/