

WE NEED A SUNSCREEN SUMMIT IN WASHINGTON DC

IN MY last column entitled “What Happened to the Drop-Dead Deadline of November 26, 2019?!” I lamented the state of the sunscreen industry and the chaos among consumers seeking protection from the sun’s harmful radiation. Of course, I blamed it all on the FDA for constantly delaying the issuance of the Final Monograph. This time I will attempt to objectively reconcile the FDA’s reluctance to finalize sunscreen regulations in the US with the status quo of where we stand today in seeking radiation protection for our consumers and ultimately reducing the spiraling incidences of skin cancer.

In all honesty, the FDA has serious issues to consider. Way back in 1978 when the Advanced Notice of Proposed Rulemaking (ANPR) was released, solar radiation protection by sunscreens was minimal. Skin cancer rates were not well documented. Available technology for designing ultraviolet filters was primitive.

At the time, achieving a tan was not so popular. People seeking the sun, and vacationing in popular resort destinations in the middle of winter were not



Do we really need another meeting? Absolutely, according to the author.

fashionable or affordable. As the incidence of skin cancer spiraled out of control, new measures for protection, including the use of sunscreen, became paramount. Today, sunscreens are used by the vast majority of US consumers. Many products are promoted for year-round daily use. Today’s sunscreen formulas are recommended for day and night use, rain or shine, and UV filters have been incorporated into a wide variety of sunscreens, skin care lotions, night creams, lip balms, hair care and anti-aging products.

More than 40 years ago, many sunscreens were poorly formulated and relied predominantly on UVB protection with little or no UVA broad spectrum protection. The sunscreen products today may contain up to six UV filters with a total percentage of UV filters well exceeding 25% of the formulation. Maximum SPF values were regulated by the ANPR in 1978 at 15, then 30 by the Tentative Final Monograph (TFM) in 1993, then 50 by the Final Rule in 2012. Yet, companies today insist that the consumer needs higher SPFs, more like 70, 100 and 100+!

Collectively, these developments have startled the FDA, sun care manufacturers

and researchers alike. When sunscreens were approved in 1978, most of the current usage was never envisioned but ultimately led to the FDA’s current stance to regulate or over-regulate sunscreens in the US.

While I am sympathetic to the FDA’s concerns listed above, US regulations have been marked with controversy and inconsistencies since their inception more than 50 years ago. For one thing, it took the FDA decades to realize that most of our 21 so-called “approved” Category I filters are inefficient molecules that predominantly protect from the UVB radiation, with few UVA molecules that are either photounstable (avobenzone) or low molecular weight aromatic ketones (the three benzophenones) that may penetrate the skin readily. The net result is the “sudden” realization that all the organic UV absorbers penetrate the skin at unsafe levels with oxybenzone recording levels of 500 times more than the FDA’s arbitrary safety level of 0.5 mg/ml!

Roadblocks to Progress

I could go on and on about other issues with deficiencies in our regulations, including testing, SPF maximum levels, quenchers and



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photostabilizers, approved and disallowed UV filters in combination with avobenzone and the rejection of the European TEA UV filters. These issues, and several others, have had a dampening effect on the progress of the industry as a whole. The FDA is to blame for failing to sound the alarm bells much earlier. The net result has been the suspension of credible research and development in promptly creating more effective UV filters, as well as developing new protocols of protection. The FDA is to blame for suppressing American ingenuity and stifling research efforts and progress by constantly delaying regulations and placing unrealistic hurdles for approval—instead of addressing those issues head-on. Lack of effective intervention by the FDA throughout those years has had a chilling effect on producing superior products and effective means of solar protection.

The recent moves and announcements by the FDA are a step in the right direction.

Now, the sun care industry is in this mess together with the FDA. It would be helpful to start a dialogue with those concerned. As the FDA now finds itself stuck between a rock and a hard place, it's time we have a real dialogue on things that matter. Skin cancer is real; it affects millions of people in the US, but protection is dismal. Better UV filters and superior protocols are desperately needed.

We Need a Summit

I wholeheartedly recommend a summit in our nation's capital to be held soon to lead us out of this dilemma. Perhaps it could be conducted under the tutelage of the FDA but include the top scientists, regulators, marketers, dermatologists and researchers in the industry along with sunscreen manufacturers, raw material suppliers and concerned organizations such as Public Access to Sunscreens (PASS) coalition, Personal Care Product Council,

Independent Cosmetic Manufacturers and Distributors, the American Academy of Dermatology, and the American Medical Association.

I might sound alarmist, but I believe we are at the crossroads of either failing our populace or, hopefully, approving sound plans that would restore the consumers' confidence in one of the many, but perhaps the most important, mode of protection by sunscreens. Sunscreen use remains a valuable protocol in the prevention of the harmful radiation responsible for the skin cancer and the skin aging epidemic we have today.

Hopefully the FDA will recognize the importance of conducting this summit soon to draw in both the consumer and all the concerned parties in the reconciliation process towards a satisfactory resolution of all the problems sunscreens are encountering today. I would love to contribute to the "agenda" of this summit! ●