

BUREAUCRACY BURNS: SQUINTING INTO THE FUTURE

RECENT DEVELOPMENTS with the FDA and the Sunscreen Innovation Act (SIA) have cast a shadow on the filter approval process in the US. In case you missed it, the FDA has basically rejected the call to speed up the approvals of the Time and Extent Applications (TEA) of the eight pending ultraviolet filters. A process that was supposed to take a maximum of one year has now been extended to over a dozen years, and there is no end in sight.¹

In an article in the Washington Post on May 11, 2015 entitled "Why the newest sunscreens still haven't hit the US market?" Reporter Brady Dennis quotes Senator Johnny Isakson (R-GA), a principal backer of the SIA, as saying, "It's going way too slow. I'm very disappointed."

It's not the first time that Isakson voiced frustration over the SIA. He asked the agency's then-commissioner, Margaret Hamburg, "Can you tell me why the FDA is so reluctant to follow through on what Congress passed in the Sunscreen Innovation Act?"²

The latest rebuff by the FDA to speed up approvals has been twofold. First, the FDA

implemented a new requirement that any new UV filters considered by the TEA process must pass the stringent requirements of GRASE (Generally Recognized As Safe and Effective), a standard that exceeds the requirements of the very costly and time consuming New Drug Application (NDA). Human absorption studies and other stringent studies now required will take months, if not years, and millions of dollars to complete. Second, the FDA asserted that access to new UV filters will make no difference since skin cancer rates are also rising in Europe, and not only in the US!

Illogical Assumptions

This assumption is illogical. Yes, it is true that skin cancer is rising worldwide especially in the Northern Hemisphere but there are many other factors that influence rates of skin cancer not just one. Primarily, poor sun protection habits lead to overexposure. More leisure time spent in the sun is part of a culture of affluence that also promotes sun drenched vacations and year-round tans as fashionable. Now, tanning beds deliver damaging UV rays indoors regardless of the season. More people develop skin cancer because of indoor tanning than develop lung cancer due to smoking (see skin cancer facts below). Additionally, superior methods of detection can diagnose skin cancer more

precisely than before so the rates have gone up accordingly.

The fact remains that the FDA has not updated our sunscreen regulations for years; most of the UV filters in use today in the US reflect the technology and expertise of the late 1970s. We have had only two additional ingredients approved at the end of the last century, namely zinc oxide and avobenzone and, more recently, ecamsule, which is exclusive to L'Oréal. An article in Slate entitled "Burned by Bureaucracy: Why is the FDA stalling on newer and better sunscreens?" author Brian Palmer wrote, "The last time a new sunscreen ingredient came on the US market, the Y2K bug was threatening to destroy our way of life. Newt Gingrich had just resigned his speakership, and Sasha Obama had not been born. Ricky Martin was on top of the charts with 'Livin' La Vida Loca,' and he was still in the closet. The point is, unlike a lot of things, American sunscreens haven't changed in a long time."³

Inadequate Options

At the risk of sounding like a broken record, our 17 approved UV filters (28 in EU and over 40 in Japan) are woefully inadequate. They are all based on technology developed in the last century that does not adequately address UVA and IR protection or photostability issues. Most of those



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**One in five
Americans will
develop skin cancer
in the course of a
lifetime.**





Action in the Senate on the Sunscreen Innovation Act is taking longer than Senator Johnny Isakson (R-GA) would like.

ingredients, with the exception of the two inorganic particulates, zinc oxide and titanium dioxide, are smaller molecules with molecular weights (Daltons) of less than 350. The new European filters are mostly based on the 500 Dalton Rule of design that prevents skin absorption, offers powerful UVA protection and are generally photostable. The insinuation that Americans should be buying their sunscreens from Europe is plastered all over the Internet. Read for example the article entitled "Why you shouldn't be buying your sunscreen in America" by Racked's Chavie Lieber.⁴

In a recent article⁵ that I wrote for New York Chapter of the Society of Cosmetic Chemists' Cosmetoscope entitled "The Road to the Sunscreen Innovation Act", I had speculated as to the impact of the SIA on our industry, namely:

1. If the four UVA filters are approved via the TEA process, the US will have far superior UVA protection in the land. Of course, this will impact the current formulations that contain Avobenzone with photostabilizers.

2. Once the European ingredients that are designed on the Dalton 500 rule are approved in the US, the need for some of the small molecule UV filters such as the cinnamates, salicylates and benzophenones would decline rapidly. Some of those ingredients have been recently implicated in phototoxicity and endocrine disrupting issues.

3. Presumably the SIA will be a catalyst

in getting the FDA to finalize the Sunscreen Monograph which will impact all the pending issues, namely:

- The maximum SPF allowed for a cosmetic product;
- The safety and use of spray products;
- The safety and efficacy of all Category I ingredients ;
- The combinations of avobenzone with inorganic filters such as zinc oxide and titanium dioxide.

Startling Statistics

May was Skin Cancer Awareness Month. Many programs and early detection centers have been set up, and numerous articles warning about the dangers of overexposure to the sun and skin cancer development have been written. I would like to share with you the recent alarming statistics included in the Skin Cancer Facts of the Skin Cancer Foundation (SCF). These facts are startling and emphasize the urgent need for better sunscreens and protocols for protection. All the highlighted facts below are credible and represent well-documented statistics from reliable sources.⁶

On skin cancer in general, SCF includes:

- Each year in the US, nearly 5 million people are treated for skin cancer. In 2006, in the most recent study available, 3.5 million cases were diagnosed in 2.2 million people.

- Each year there are more new cases of skin cancer than the combined incidence of cancers of the breast, prostate, lung and colon.

- One in five Americans will develop skin cancer in the course of a lifetime.

- Between 40 and 50% of Americans who live to age 65 will have either basal cell carcinoma (BCC) or squamous cell carcinoma (SCC).

On melanoma, SCF points out:

- One person dies of melanoma every hour (every 57 minutes).

- An estimated 73,870 new cases of invasive melanoma will be diagnosed in the US in 2015.

- About 86% of melanomas can be attributed to exposure to UV radiation from the sun.

On tanning, SCF reports:

- Ultraviolet radiation (UVR) is a proven human carcinogen.

- More than 419,000 cases of skin cancer in the US each year are linked to indoor tanning, including about 245,000 BCC, 168,000 SCC, and 6,200 melanomas.

- More people develop skin cancer because of tanning than develop lung cancer due to smoking.

- Eleven states now prohibit indoor tanning for minors younger than the age of 18: California, Vermont, Nevada, Oregon, Texas, Illinois, Washington, Minnesota, Louisiana, Hawaii and Delaware.

- Brazil and New South Wales, Australia, have passed complete bans on indoor tanning. As of January 2014, France, Spain, Portugal, Germany, Belgium, the UK, Iceland, Italy, Finland and Norway prohibit indoor tanning for youths under age 18.

Finally, on skin aging and treatment, SCF lists:

- More than 90% of the visible changes commonly attributed to skin aging are caused by the sun.

- Daily sunscreen use by adults under age 55 can reduce skin aging.

- The annual cost of treating skin cancers in the US is estimated at 8.1 billion dollars.

- Estimated annual productivity losses attributable to melanoma total 2.85 billion dollars.

Please share all of these statistics from the Skin Cancer Foundation with your family and friends.

A New Resource Is on the Way

A new book entitled "Principle and Practice of Photoprotection" is due to be published by Springer in 2016 and will include contributions from the top scientists and dermatologists worldwide. Drs. Henry Lim and Steve Wang (a past Sunscreen Filter contributor) are on the Skin Cancer Foundation's advisory board and have recently embarked on editing this reference manual. I was honored to participate in writing the introductory chapter entitled "The Chemistry of Ultraviolet Filters." This book will provide an update to my own edited book published in 2005 by Taylor & Francis entitled "Sunscreens: Regulations and Commercial Development." Make sure to get your copy of their book when published.

In conclusion, constant analysis of the efficacy of photoprotection using UV filters is required to stem the skin cancer crisis. However, new technologies and advances

in UV science alone cannot provide the full protection from the sun that we need. Without bureaucratic flexibility in the approval process, US consumers are left out in the cold. We have demanded a resolution to the TEA approval process but, as of now, there is no end in sight.

It is important that we continue our work to improve our sunscreen products so that the incidence of skin cancer does decrease in the years to come. Instead of getting discouraged, maybe it's time to redouble our efforts and put some real pressure on the FDA. If not, who could blame American consumers for looking elsewhere for more sunscreen products that have their science in the 21st century.

In addition, the stifling of ultraviolet filter R&D efforts in the US is unconscionable. Lessons should be learned from this unproductive time. Incentives must be given, and faster routes to market superior UV filters must be facilitated and approved,

including new and improved methods to reverse the early onset and developing stages of skin cancer. It is my hope that research into new ingredients and better protocols of protection are encouraged. Innovation in ultraviolet filter research has been sorely missed in the US! ●

References:

1. The FDA Response: Obstacles and Delays, "The Sunscreen Filter", Nadim A. Shaath, HAPPI, April 2005.
2. Brady Dennis, The Washington Post, May 11, 2015, "Why the newest sunscreens still haven't hit the US Market?"
3. Burned by Bureaucracy: Why is the FDA stalling on newer and better sunscreens?, <http://www.slate.com/articles/health>
4. <http://www.racked.com/2014/7/16>
5. Nadim A. Shaath, Cosmetoscope, Vol.21, No. 3, March 2015.
6. <http://www.skincancer.org/skin-cancer-facts>