

# AFTER 50 YEARS OF SUN CARE...

**A**S WE CELEBRATE 50 years of sun care developments in the US, we pause to reflect on our accomplishments as well as our disappointments. There have been both innovations and delays in sun protection. Tom Branna, editor of HAPPI, has already written an article on the topic and predicted, "If one were to forecast the sun care market's fortune for the next 50 years, it would surely be sunny, with a few scattered clouds." (HAPPI, December 2013). He added, "To sum up about sun protection, it's clear that there's been lots of good news, some bad news and many issues that are still making the news. I concur with Johnson and Johnson's Dr. Curtis Cole who commented that much of his career has been following (or chasing) the FDA and the elusive Final Sunscreen Monograph. We have waited a long time. I hope I will be alive when it finally happens! I trust that the New Year will bring new developments. Let me summarize the most important developments in the last two months of 2013.

## Delays

Our efforts through the PASS Coalition to seek the support of the US Congress to work collaboratively with the FDA in reforming the current sunscreen approval process has yielded mixed results. On Friday, November 15, the House Energy and Commerce Subcommittee on Health held an FDA oversight hearing with Dr. Janet Woodcock, MD, director of the FDA Center for Drug Evaluation and Research (CDER). Representatives Whitfield (R-KY) and John Dingell (D-MI) pressed Dr. Woodcock on the significant delays of eight sunscreen ingredient applications (the so-called TEA applications) whose approval has been pending before the FDA for more than a decade.

"We are more frustrated than the manufacturers and you all are about this situation," she responded. "The problem is that we have to do regulations to get these ingredients into monographs and they are backlogged and slow to get through."

A slow moving bureaucracy leads to unnecessary delays. A clip of the exchange can be viewed on C-Span.<sup>1</sup>

## Negotiations

Bipartisan legislation is being drafted by Senators Jack Reed (D-RI) and Johnny Isakson (R-GA) along with Representatives John Dingell (D-MI) and Ed Whitfield (R-KY) to reform the sunscreen application process to ensure that new sunscreen ingredients receive a transparent review within a predictable time frame. In the hearing, Rep. Whitfield asked Dr. Woodcock when Congress could expect technical assistance regarding the legislation that had been sent to the FDA in June 2013. On Nov. 26, 2013 that Technical Assistance (TA) was actually sent by the FDA to Congress. Despite the fact that the TA was drafted by the FDA's lawyers to protect its current regulatory

process, it now begins the negotiating process between Congressional staff, the FDA and the PASS Coalition. Stay tuned for upcoming developments!

## "Unified Agenda"

On the same day that the FDA sent the TA to Congress (November 26), the FDA also issued its Fall 2013 "Unified Agenda" establishing its projected timeline for action on pending regulatory activities in sunscreens. As expected, the FDA delayed the projected timeline for action on the pending OTC applications for sunscreen products. This is the tenth time since 2008 that the FDA has delayed action on the OTC sunscreen applications—despite assurances to Congressman John Dingell that action would be taken on the OTC sunscreen applications by November 2013.

As my friend David Steinberg told me a few years back about the Unified Agenda: "It's for all those who believe in science fiction." He further remarked that the TEA ingredients would be approved by the FDA "when we have world peace and I win the Powerball and my son grows wings and flies!"

Without losing all hope, many feel that swift FDA approvals are not likely and David will not win Power-ball any time soon.

## Sun Care Safety

The Annual Meeting of the Society of Cosmetic Chemists was held in New York December 12-13. The highlight was the 2013 Frontiers of Science Award lecture by Dr. Joseph Schwarcz from Montreal's McGill University and also a mini symposium on "The Evolving Science and Regulation of Nanomaterials Affecting the Personal Care Products Industry" which featured four lectures on the topic. A risk review in sun care presented by Croda scientists concluded "the vast majority of the data in the studies still



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recognizes that ultrafine TiO<sub>2</sub> and ZnO are safe for use in sun care applications and offer excellent protection against UV radiation.”<sup>2</sup>

In Australia, however, the controversy over the safety of nanoparticles continues with Friends of the Earth still alleging that Antaria and Ross Cosmetics falsely claimed that their formulations were nano-free.<sup>3</sup> The Australian Competition and Consumer Commission (ACCC) has rejected the complaint citing a lack of any legal definition of nanomaterials in Australia.

## Optimal Protection

In my November 2013 column of “The Sunscreen Filter” I highlighted two landmark studies by Dr. Adelle Green<sup>4</sup> and another by Dr. Elke Hacker and her associates.<sup>5</sup> The study by Dr. Hacker concluded that sunscreens not only provided 100% protection against all three forms of skin cancer, but it also shielded the important p53 gene, a gene that works to prevent cancer.

On the other hand, in the Dec. 4, 2013 issue of the *Journal of the American Medical Association (JAMA Dermatology)*, Dr. Frank Wang, MD, and his associates from the University of Michigan Medical School measured the effects of UVA1 radiation (340-400nm) at the molecular level using advanced gene expression analysis of skin samples from the buttocks of 22 human volunteers. After just two exposures, UVA1 rays caused skin cells to make molecules that break down the collagen. The UVA1 also caused the skin to darken with each exposure, but this tan did not protect against further production of the enzyme MMP-1 (Matrix Metallo Proteinase 1), the collagen destroying molecule, when the skin was exposed to more doses of UVA1. Dr. Wang and his colleagues concluded, “For optimal protection against sun damage, sunscreen formulations should filter all UV wavelengths, including UVA1 radiation.”<sup>6</sup>

## Innovative Ingredient

Researchers at the University of Bath in

the UK have reported on a new molecule that protects against the damaging UVA rays. Dr. Charareh Pourzand and Dr. Ian Eggleston from the Department of Pharmacy and Pharmacology have created an innovative ingredient that acts as a UVA filter and provides fuller protection against skin damage. When the skin is exposed to the UVA component of sunlight, iron is released which produces free radicals on the skin by interacting with fat, protein and the DNA of the cells. These free radicals have been shown to play a key role in skin aging and the onset of skin cancer. The new compounds are light-activated when exposed to relevant doses of UVA. These “caged-iron” chelators could provide a highly effective means of protection against both UVA and UVB induced skin damage and associated skin cancer, without inducing toxicity in cells.<sup>7</sup>

## Photoprotection

Finally, a group of dermatologists and scientists in Michigan, New York and Germany have collaborated to write an excellent review on “Photoprotection.” Part I deals with photoprotection by naturally occurring, physical and systemic agents. Part II deals with sunscreen development, efficacy and controversies.<sup>8</sup> It is a must read!

## A New Era

We can imperfectly protect people from the damaging effects of the sun. A review of the sun care innovations of the past half century reveals discoveries and developments that have changed our relationship to the sun. Our advances in scientific understanding and technology are impressive but do not always match with what is provided to the consuming public. There is a disconnect between what science can offer and the sun care products available on the market. This New Year ushers in a new opportunity to protect those who seek to protect themselves with sun care products; we must approve better filters.

With 2013 over, the New Year presents some real challenges, it’s easy to dwell

the FDA’s ongoing reluctance to approve the Final Sunscreen Monograph, which may indeed be as elusive as world peace. Yet, the New Year brings with it the promise of some new developments in our ongoing goal of bringing the finest, most-effective sun care products to the consumer to combat our biggest challenge—skin cancer.

If we don’t lose sight of the big picture, there is much we can celebrate about our first 50 years. Let’s hope the next 50 are just as productive and just as exciting.

Best wishes for a happy and productive 2014! ●

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