

# Sunscreen Developments Need Bipartisan Government Support

**T**he PASS Coalition, of which I am a member, went to Washington on May 5! It was not exactly a “filibuster” or Jimmy Stewart’s appeal to Congress, but it was extremely helpful to voice our frustrations and concerns for timely sunscreen regulations in the land. We met with staffers of the Senate’s Majority and Minority HELP (Health, Education, Labor, Pensions) Committees, as well as the staffers of Senators Jeff Merkley (D-OR) and Jack Reed (D-RI) and Representatives John Joyce (R-PA), Ed Case (D-HI) and Dave Joyce (R-OH). Previously, we had also met with Senators Marc Rubio (R-FL), Brian Schatz (D-HI), Patty Murray (D-WA), Roger Marshall (R-KS) and Representative Bob Latta (R-OH).

We voiced our grievances and concerns along with our opinions on how we view the progress in regulations today. We trust that the above Senators and Congressmen and Congresswomen will address all of our issues with the FDA soon, especially now that Dr. Robert Califf has been appointed the FDA Commissioner.

In other regulatory developments, the Final Report of the National Academy of Sciences (NAS) investigating the impact of

## Nadim Shaath

Alpha Research & Development Ltd

Nadim@alpharnd.com



Dr. Nadim Shaath is the president of Alpha Research & Development, Ltd. in White Plains, NY. He has over 30 years of experience in the sunscreen industry. He served as the Chairman of the chemistry department at SUNY-Purchase and the CEO of Kato Worldwide. Recently he published his new book entitled “Healing Civilizations: The Search for Therapeutic Essential Oils and Nutrients” Cameron Books, Petaluma, CA.



When lawmakers won't come to you, you go to the lawmakers.

The PASS Coalition visited Congress last month.

sunscreens on the environment, especially coral reefs, was scheduled to be released in February. We understand that it may now be released by mid-summer at the earliest. Its findings will undoubtedly have a major impact on the sunscreen market. Also, the Appropriations process in Congress is steadily progressing with the House ready to issue the final proposed budget. The Senate will probably require an additional four to six weeks to finalize the budget prior to September 2022 when current funding lapses. Soon we should hear about the funding to the FDA and sunscreen developments—including user fees.

Hopefully, the issues with regulations in the 2019 FDA proposed order will be addressed soon. These issues include:

- The Final GRASE (Generally Regarded as Safe and Effective) status of the eight UV filters (Avobenzone, Octocrylene, Octisalate, Homosalate, Oxybenzone, Octinoxate, Meradimate and Ensulizole).
- The Final approval status for use in the US of the six TEA (Time and Extent Application) European filters. At this stage only Bemotrizinol (Tinosorb

S/Escalol S) is under consideration for approval.

- Addressing the right of “states” to overrule the FDA to ban or approve UV filters or sunscreens and to require “prescriptions” for the use of OTC products on the market, based on what is happening in Hawaii and in California.

A host of other issues, too many to list here, including the UVA testing and protection, the SPF ceiling, and the use of combination sunscreen-insect repellent products have yet to be debated.

In other recent developments, we were informed that the upcoming meeting between the FDA and the Personal Care Product Council that was supposed to be held in April was postponed to the Fall. The FDA simply does not like to meet with companies, organizations or individuals. It also rarely responds to letters sent to its organization. We hope that our upcoming planned letter to Commissioner Califf will finally elicit a response. Also, recently, the EWG (Environmental Working Group) released its 2022 Sunscreen Report. Most of the issues have been addressed in their

earlier annual reports. Other issues addressed included the quality of European sunscreens versus those produced in the United States, the troubles with ingredients in current sunscreen formulations, and the confusion with SPF ratings.

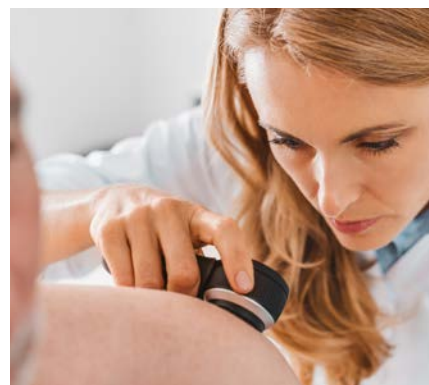
Last month was Skin Cancer Awareness Month. It was commemorated with the setting up of sunscreen testing stations in numerous locations, including Congress, and the dissemination of information for solar protection by skin cancer and melanoma organizations. It is worthy to note again that one in five Americans are expected to get skin cancer at some point in their life before the age of 70. Every hour, one to two people die of skin cancer in the USA. The need for photoprotection is paramount.

### **ROOM FOR GROWTH IN THE US**

As you may have noticed already, the

majority of my columns have focused on sunscreen regulatory issues rather than reporting on research developments or addressing the improvements in sunscreens and novel ultraviolet filters that offer superior protection from the ravishing rays of the sun to reduce the incidences of skin cancer cases. I am not addressing advancement in those latter issues simply because there is a dearth of information on the subject. When did you hear last about a new superior UV filter in the US? You haven't! Where are the epidemiological studies and basic research in the US that document the protection offered due to sunscreen use in protecting from the harmful solar radiation? There are almost none!

I could go on and on about research and data desperately needed to resolve the issues that confront UV filter and



One in five Americans are expected to get skin cancer before the age of 70.

sunscreen development and, most importantly, warding off solar radiation that will ultimately lead to the reduction, or elimination, of skin cancers. Perhaps some of these questions will be addressed in President Biden's reignited Cancer Moonshot program. Only time will tell. ■