

MISINFORMATION SURROUNDS PANDEMIC HEADLINES

DISINFECTANT EFFECTIVELY kills viruses. Should we ingest it or inject it into our bodies? Ultraviolet light and sunlight reduce the virus population. Should we frequent tanning salons and overexpose ourselves to the harmful UV rays? The answer to both those questions is very obviously “No!” I will not dignify the first question with an answer, but the second disregards information dissemination since the middle of the last century concerning the hazards of UV radiation in promoting skin cancers.

May was Melanoma Month and organizations throughout the country advised people to avoid the sun and seek protection by using effective sunscreens and other safety measures. The incidences of skin cancer have skyrocketed to almost five million new cases annually. A study sponsored by both NYU Grossman School and Harvard University was released earlier this year and received minimal attention due to the coronavirus pandemic in the US. Advances in skin cancer treatment have



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led to the largest yearly decline in deaths due to melanoma ever recorded for this skin cancer. This 30-year study (1986 to 2016) reviewed new systemic therapies and trends in cutaneous melanoma deaths among the US white population. The study showed that death rates among white Americans—the group that accounts for almost all cases—climbed 7.5% between 1986 and 2013, but dropped nearly 18% during the next three years. The death rates were for metastatic melanoma, the aggressive form that spreads from the skin to other organs such as the lung, liver or brain. The most recent results are very promising numbers.¹

Meanwhile, the US Congress voted on its 2020 Appropriations bill in December of 2019 and included in the budget was the creation of a Task Force to “conduct a review of the current scientific literature of existing marketed sunscreen ingredients using standard federal reliability guidelines for toxicity data to

determine the potential risk to the marine environment.”² This will include “a review of existing hazard and exposure data encompassing both ecological and animal toxicology endpoints for these chemicals. The committee will provide recommendations for additional research to be undertaken that will generate the data required to conduct a marine environmental risk assessment of currently marketed sunscreen ingredients, including recommendations on testing methods, study designs and research priorities. To complement human safety data currently being collected by the Food and Drug Administration (FDA), the committee will also evaluate the need for risk mitigation focusing on development of a comparative risk assessment balancing the risk posed by sunscreen ingredients to the marine environment with the potential public health implications associated with reduced use of sunscreen for protection against excess ultraviolet radiation exposure.”²



Nadim Shaath
Alpha Research
& Development Ltd
Email: alphamd@aol.com

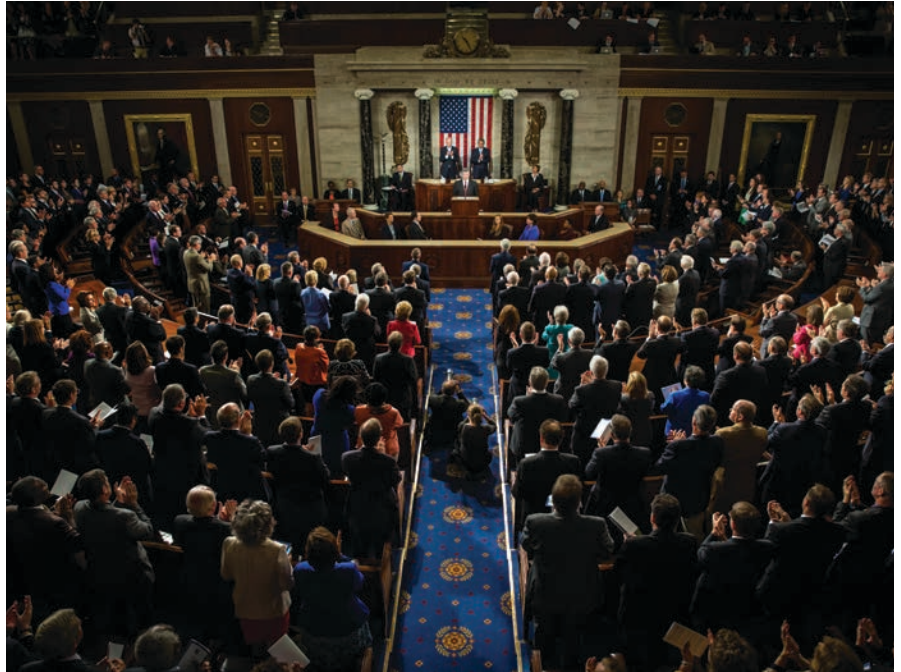
Dr. Nadim Shaath is the president of Alpha Research & Development, Ltd. in White Plains, NY. He has over 30 years of experience as chairman of the chemistry department at SUNY-Purchase and the CEO of Kato Worldwide. Recently he published his new book entitled “Healing Civilizations: The Search for Therapeutic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

Agency Meetings

Even though the study's focus was on the risk to the marine environment due to the negative findings that oxybenzone and octinoxate were recently implicated in damaging Hawaii's coral reefs, we were encouraged that two statements were included in the task assignment. These were "the potential public health implications" and "to complement human safety data currently being collected by the FDA." Members of the PASS Coalition (Public Access to Safe Sunscreens), of which I am a member, organized several meetings in the past two months with the Environmental Protection Agency (EPA), National Academy of Science (NAS) and National Oceanic and Atmospheric Administration (NOAA). The first meeting was held on March 18 with NOAA and met with Brandon Elsner and his staff. On March 20 PASS met with Jennifer Orme-Zavaletta and her staff at EPA, and on April 23 with Dr. Susan Roberts and directors of three boards at NAS.

In our meeting with NOAA, we voiced our concerns that the agency is disseminating inconsistent information about the damage to the coral reefs resulting from selected UV filters. We alluded to the more prominent factors that may be contributing to the damage to the coral reefs including Surface Sea Temperature (SST), prolonged warming periods, ocean acidification, pollution and other environmental factors beyond the use of sunscreens by beachgoers. We also pointed out that the actual studies are limited and have been conducted in the laboratory and not at the coral sites.

The Appropriations bill tasks the EPA to request NAS to conduct a thorough review of all these factors. The meeting with the EPA was very productive, but they informed us at the time that they still have not received the official charge from Congress. EPA promised to keep us involved and seek our assistance and clarifications where appropriate. Finally, in our April meeting with NAS, they informed us that as soon as they receive



It doesn't matter what side of the aisle you're on; there must be sunscreen regulation reform.

the project from the EPA they will be forming a panel to study the tasks required of them to conduct, and would seek us out for nominations to possibly include on their panels. Progress, but it is the slow wheels of government turning. Even though the project is for 18 months, I predict that it will take many more months, if not years, to properly complete.

Congressional Actions

My column last month highlighted the provisions' impact of the CARES Act.³ On March 27, the House Bill (HR748) mirrored what the FDA issued on Feb. 26, 2019 as the Proposed Final Rule for Sunscreens.⁴ More importantly, however, two more provisions were added by Congress. The first introduces an "Administrative Order Process" that would replace the current notice-and-comment rulemaking. This process allows the FDA to deny a hearing if it so chooses. The second is the sunset of the Sunscreen Innovation Act (SIA) in 2022. This gives the FDA power to make all the decisions concerning the Final Rule without active opposition if it chooses to exercise these provisions.

FDA has had that power since its

inception and look where we are now. Consumers are totally confused about the safety and effectiveness of sunscreens. States are banning UV filters without consulting the FDA. Only two filters, ZnO and TiO₂, which represent about 7% of the sun care formulations, are designated as Generally Regarded as Safe and Effective (GRASE). All the other filters, which represent 93% of sun care formulations on the market today, must undergo extensive, expensive testing before they can be approved for use in the US. No European filters are permitted to date despite their demonstrated safety and effectiveness all over the world for a decade or more. No Final Monograph exists today—more than 40 years after issuing the first regulations in the US. This cannot be promising! ●

References:

1. Juliana Beck-Kraus, Jennifer Stein, Jeffrey Weber and Alan Geller. New systemic therapies and trends in cutaneous melanoma deaths among US whites, 1986-2016. *Amer. J. of Public Health*, 2020, March; 110 (5); 731-733
2. www.congress.gov/resources/display/content
3. www.congress.gov/bill/house-bill/748/content
4. *Federal Register*/Vol. 84, No. 38, Feb 26, 2019.