

Will FDA Commissioner Califf Make Sunscreen a Priority?

After many months of Congressional hearings, there is finally a new FDA commissioner. Dr. Robert Califf, a cardiologist who served as the FDA chief during the Obama Administration, was confirmed on February 15 by a very small majority (50-46) in the Senate. He was opposed by five key Democratic senators (Sanders, Manchin, Hassan, Blumenthal and Markey) for his prior work with the pharmaceutical industry and his lax record on opioids.

The issue of opioids had derailed the nomination of Dr. Janet Woodcock, the Acting Commissioner, earlier and she will now serve as the Principal Deputy Commissioner (second in command). The FDA currently faces major issues with the decisions to approve additional new corona vaccines, especially for children younger than five years old, and a host of other controversial issues including the abortion pill, flavored e-cigarettes, an Alzheimer drug and the opioid crisis. But nowhere in the nomination hearings were the controversial issues related to sunscreens ever extensively addressed!

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.



Xavier Becerra, Secretary of Health and Human Services, ceremonially swears in Dr. Robert M. Califf as FDA's Commissioner of Food and Drugs during a ceremony at the Health and Human Services headquarters in Washington, DC on Feb. 22, 2022. Califf was joined by his spouse, Lydia Califf.

The ceremonial event followed Califf's official swearing in that occurred Feb. 17, 2022.

(US Food and Drug Administration photo by Matthew MacRoberts)

The FDA regulates 20% of the dollars spent by consumers (prescription drugs, most of the nation's food supply, and cosmetics including sunscreens, etc.) but has given sunscreen regulations an extremely low priority. Hawaii has consistently usurped the responsibilities of the FDA by unilaterally requiring both drug prescriptions to use sunscreens and banning most currently approved UV filters from use (see Happi, February 2022, p. 48). These two functions are obviously FDA functions and not state functions. Hawaii today has numerous bills to ban and regulate ultraviolet filters on the basis that they harm the coral reefs. These include HB 1519, SB 2319, SB 2850, SB 2910, SB 2949 and SB 3001. If passed, they would ban all non-GRASE (Generally Regarded as Safe and Effective) ultraviolet filters from being sold in Hawaii. This effectively means that sunscreens with only mineral titanium and zinc oxide filters would be allowed in Ha-

waii in the future. Of course, if the FDA would ever get to issue the "Sunscreens Deemed Final Order" (which refused to make determinations regarding whether many ingredients commonly found in sunscreens are GRASE) and eventually allow the use of the other 12 traditional non-mineral UV filters, then perhaps that would change the landscape in Hawaii and other worldwide municipalities advocating only mineral sunscreens.

A QUIET FEW MONTHS

The sunscreen category has been relatively quiet of late. However, an interesting study conducted at Griffith University in Queensland, Australia, found that aerosol sunscreens did not adequately deliver sunscreen in mildly windy conditions leading to poor protection against UV radiation. Researchers tested five aerosol sunscreens and found that at a moderate speed of 12 mph, 28-93% sunscreen was lost and

at low speeds of 6 mph the loss was 32-79%. Despite the wide range of loss based on these initial findings reported in the study, the Cancer Council, the Radiation Program, and the Nuclear Safety Agency of Australia strongly urged Australians against using aerosol sunscreens for sun protection this summer!

In other news, the National Cancer Institute in the US relaunched its “moonshot” effort to reduce incidence of all cancers by 50%. The campaign was introduced by then Vice President Joe Biden during the Obama Administration. I hope this program funds US researchers to document the efficacy of sunscreens’ ability to protect from skin cancer. Very little research on this subject has been carried out in US universities and pharmaceutical companies. Australian researchers have led the way

in this endeavor. The role of sunscreens in real protection from skin cancers must be properly documented!

Research into new, more effective safe ultraviolet filters has been seriously lacking worldwide. Here are a few attempts today. Russian chemists (in the *Journal of Materials Chemistry B*) revealed that tetravalent cerium phosphates were comparable in protection to commercial titanium and zinc oxides. In a previous column (February 2021) I reported on a bacterium (*Bacillus lysate*) with excellent SPF boosting capabilities. The bacterium was discovered on the International Space Station. Attempts to commercialize this material are underway.

While some researchers search the heavens, others scour the ocean for sunscreen solutions. Their research has focused on micro algae, cyanobacteria, sea

cucumbers, seagrass, mangroves, planktons and, most recently, Zebrafish. Several of these marine materials have potential in UV protection. However, due to issues of cultivation, purification and isolation, the ability to yield commercially available safe and effective UV filters is still years away. When, and if, these new ingredients are finally harnessed and commercialized, convincing the FDA to approve them as GRASE filters for sunscreen human use will be a major challenge!

A seismic shift in priorities at the FDA is required to give sunscreen regulations a higher priority to enable us to create superior UV filters and ultimately better and safer sunscreen products to decrease the incidences of skin cancer observed today. I’ll close with some good news. After two years, FDA has agreed to meet with PCPC. ■