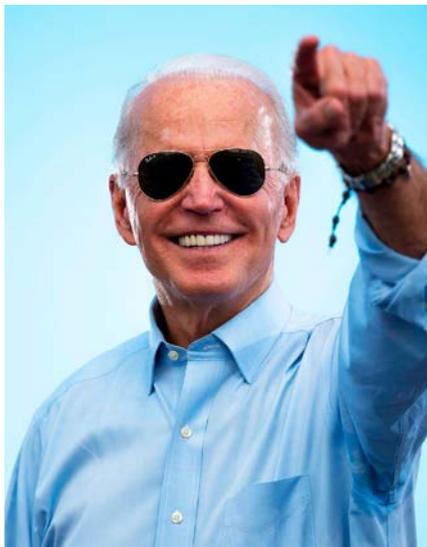


The Politics of Sunscreens Are Heating Up

This column will be totally devoted to reviewing the political scene in sunscreens as the new Biden Administration is settling in. First, Javier Becerra, the nominee for Secretary of Health and Human Services (HHS), faced fierce opposition in the Senate, but was finally confirmed on March 18 by a slim vote of 50-49, with Republican Susan Collins of Maine crossing the aisle to join Democrats in confirming Becerra.

With his confirmation, Becerra becomes the first Latino to hold this office. He is expected to pursue liberal issues on abortion, criminal justice and immigration. It is not clear what his impact will be on sunscreen regulations, but he was criticized in the Senate for his lack of medical experience.

As for the Commissioner of the FDA, two names are being circulated for the post, namely former Deputy FDA Commissioner, Joshua Sharfstein, and Janet Woodcock, Director of CDER (Center for Drug Evaluation and Research). Dr. Woodcock, I am told, will probably be the likely nominee despite her stance during the recent opioid epidemic. Woodcock was a central figure at FDA when Purdue Pharma's OxyContin was approved as a painkiller. Still, she would probably not face major opposition in her Senate confirmation. The appointment of



US President Joe Biden's cabinet picks will impact the sun care market.

both the HHS Secretary and the Commissioner of the FDA are two critical posts that will dictate the future of sunscreens in the USA. Why? Because the FDA is poised to issue its final Administrative Orders (AO) on sunscreens by September 2021!

PASS IN WASHINGTON

The PASS (Public Access to Safe Sunscreens) Coalition has been extremely active in lobbying members of Congress in February. I have attended meetings with the staff of five Senators (Brian Schatz, D-HI; Patricia Murray, D-WA; Richard Burr, R-NC; Jack Reed, D-RI and Chris Murphy, D-CT) and five Congressmen (Bob Latta, R-OH; Ed Case, D-HI; John Joyce, D-PA; Kai Kahahele, D-HI and Brett Guthrie, R-KY). These 10 legislators are involved in the Energy and Commerce Committee, the Health, Education, Labor and Pensions (HELP) and the Appropriations Committee in both the House and the Senate. They are among the key members in Congress that can influence the FDA and its final decisions on the sunscreen monograph. The meetings were quite productive where the coalition advanced its

platform of both the need for access to safe sunscreens for protection and the challenges at the FDA.

The PASS Coalition's position was simply that Americans need access to education on sun-safe practices and more importantly to the latest sun protection technology, to keep themselves safe from UV radiation. The use of sunscreens is one of the most important protective regimens in the tool-box of prevention. We called for the approval of the six Time and Extent Application (TEA) ingredients and for reinstating of some of the effective UV absorbing molecules that the FDA recently relegated to Category III status (requiring further safety testing). We stressed the fact that a sunscreen industry relying solely on the use of the mineral inorganic filters of ZnO and TiO₂ is impractical and insufficient in providing consumers the necessary protection from the harmful radiation.

We met with the staffers of two Congressmen and the Senator from Hawaii to review the legislation currently being proposed and the impact of banning two UV filters from sale and use in Hawaii. Currently there is a House Bill (HR 102) and a Senate Bill (S 132) which are debating the banning of many more UV filters from sale and use in Hawaii. The House Bill has been effectively postponed until the conclusion of the National Academy of Sciences (NAS) study that is underway in Washington DC. The Senate bill, however, had recently reevaluated a few more UV filters that it wishes to ban (avobenzone and octocrylene, instead of octisalate and homosalate). This is obviously in addition to oxybenzone and octinoxate bans which went into effect January 1, 2021.

In a hearing on March 16, the bill in the Senate was postponed to July 1, 2050 to "encourage more discussion"! Meanwhile, a recent joint study from France and the US entitled "Benzophenone accumulates over time from the degradation of octocrylene in commercial sunscreen products" found that benzophenone (banned under California Propo-

Nadim Shaath
Alpha Research &
Development Ltd
alphanrd@aol.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.

sition 65) was detected in all octocrylene commercial products tested when subjected to an accelerated stability testing protocol for six weeks. The researchers concluded that octocrylene/benzophenone found in products can pose a threat to public health.¹

The National Academy of Sciences is undertaking a study on behalf of the Environmental Protection Agency (EPA), which had received funding from Congress in 2020 after the PASS Coalition lobbied Congress to study the issues related to the Hawaii ban of UV filters. The NAS panel held a public meeting on February 23 and another closed-door meeting on March 2 in which they very broadly discussed their mission. The NAS Engineering and Medicine (NASEM) panel is comprised primarily of marine eco-toxicologists with environmental concerns and a few dermatologists and cancer epidemiologists. Conspicuously absent from the NASEM panel are any members with expertise in FDA sunscreen regulations or knowledge in the chemistry of ultraviolet filters!

FDA MISSTEPS

The proposed ruling by FDA in February 2019 and the subsequent CARES Act Bill in March of 2020 have produced serious uncertainties among consumers nationwide and, specifically, the legislature in Hawaii. The Hawaii Reef and Ocean Coalition and the Friends of Hanauma Bay incorrectly keep pointing to the FDA's 2019 proposed rule to show that only zinc oxide and titanium dioxide are safe for human use. They keep using the Generally Regarded as Safe and Effective (GRASE) list of approved UV filters as "proof" that the FDA says that these are the only two filters that are allowed! These are the legislators that are presumably informed and in control; what would you expect from the average consumer? Despite the fact that the FDA has repeatedly said that the Category III ingredients (those requiring further safety data) **are** allowed until they issue their final Administrative Order, consumers seem to have made up their minds that zinc oxide and titanium dioxide are the only two filters that are permitted in sun care products!

My column is highlighting the politically charged debates on all levels of the spectrum of those involved in the regulation, manufac-

turing and ultimately use in protection from the harmful rays of the sun. The FDA's incomplete decisions throughout the past 40 years, culminating with the recent proposed final regulations in 2020 and including its MUSt studies revealing the penetration of the UV filters into the blood, has perhaps done irreparable harm in our battle to pro-

duce effective sunscreens that can assist in combating the skin cancer epidemic we are experiencing today. ■

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