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EDITORIAL

Safer and More Broad-spectrum Ultraviolet Protective Sunscreens Available in Other Countries: Need FDA Approval for Public Health of Americans STAT

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Chronic UVA exposure induces damage to human skin. Higher wavelengths tend to penetrate deeper and are thought to induce a myriad of skin conditions, thereby playing a significant role in the photoaging process [1, 2]. Modern sunscreens should provide protection from both UVB and UVA radiation while also maintaining this protection during the entire period of exposure to the sun. Present chemical UVA filters in America, however, do not adequately cover the UVA spectrum and are not sufficiently photostable. They are inferior to products available in other countries, including Europe, Japan, and Canada.

The active ingredients in sunscreens are either mineral filters (such as zinc or titanium oxide) or the more commonly used chemical filters [1, 2]. The mineral filters are stable and work immediately when applied. They may leave a white cast unless the particles are pulverized into nanoparticles. Chemical filters need to be on the skin surface for twenty minutes before they properly absorb ultraviolet light. Most sunscreens combine two to six chemical filters, while some combine zinc oxide with chemical filters. These broad-spectrum sunscreens have limitations, such as degradation under ultraviolet exposure, which result in their decreased effectiveness. Moreover, the chemical filters are absorbed, and oxybenzone that is present in 70% of sunscreens, can be detected in almost all Americans [3]. Chemical filters used in America have been reported to have negative health impacts (*i.e.*, hormone disruption, vitamin D deficiency), trigger skin sensitivities and allergies, cause photoallergic reactions, and/or play havoc with the environment (*i.e.*, destruction of coral reef) [4].

Sunscreens have been regulated by the Food and Drug Administration (FDA) since the 1970s. With the release of new FDA testing and labeling requirements in 2011 and the enactment of the Sunscreen Innovation Act in 2014, sunscreen manufacturers are now required to evaluate their products not only on the basis of sun protection factor (SPF) but also on broad-spectrum UVA protection [1]. More recently, in 2019, FDA proposed new rulings on sunscreens revising requirements in terms of active ingredients, maximum sun protective factor (SPF) that assesses UVB coverage, and labelling [5]. They reiterated a need for better broad-spectrum products that protect against UVA and UVB rays [5]. One of the factors in the monograph of the 2020 Coronavirus Aid, Relief, and Economic Security Act (also known as the CARES Act) was to label the present chemical filters in America as "generally recognized as safe and effective" (or "GRASE"), and therefore, they could continue to be marketed without a new drug application and pre-market approval [6]. It also deferred any action on the GRASE ingredient in terms of safety or efficacy, while acknowledging such complaints about these chemicals. The ruling failed to mention any of the chemical filters available in other countries presently.

Thus, the FDA has several safety and effectiveness regulations in place that govern the manufacture and marketing of all sunscreen products, including safety data on its ingredients. Problems, however, exist. A major issue is that FDA is a cumbersome and overextended entity that is asked to monitor too many products without the tools, funding, manpower, or time to complete tasks. They oversee more than 20,000 prescription drug products, 65 separate categories of medical devices, 90,000 tobacco products, 78% of US food supply, and consumer products from laser pointers, deodorants, pet food, perfume, tampons, and microwave ovens, and sunscreens. In the area of dietary restrictions and supervision, Matt Seigel states "the majority of food facilities under their jurisdiction (56%) go more than five years without inspection and a much larger percentage (about 99%) of the imported foods they are responsible for go uninspected completely...So no agency is really in charge of nutrition, transparency, or labeling, and we are basically on the honor system [7].

In the case of sunscreens, FDA actions have been even more belated while attaching excessive regulations that are never fulfilled. Minimal progress for the general public has

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been achieved [8]. Europe, Japan, Canada and other countries have had access to better sunscreens (Mexoryl, Tinosorb, Uveinul A) for almost two decades [9, 10]. Mexoryl, a novel ultraviolet A filter, provides efficient ultraviolet A coverage, better photostability, and enhanced water resistance. The FDA has minimally addressed these products' issue and has delayed acceptance, suggesting that there is insufficient research. The exception is Mexoryl SX which L'Oreal obtained registration under a New Drug Application in 2006. Although approved, this product is much higher priced in America than elsewhere, limiting its usage.

The refusal to introduce these new sunscreens is glaring in light that the FDA has decreed that all present chemical sunscreens available in America are unsafe but presently under more review before the final assessment. Furthermore, the FDA suggests that physical sunscreen (namely titanium dioxide and/or zinc oxide) is safe. However, they fail to note that when pulverized to a small size, they can be a major concern to aquatic animals as well as being absorbed into humans directly. Nano zinc oxide particles smaller than 100 nm can be ingested by murine life, causing internal damage. Furthermore, particles smaller than 30 nanometers can be absorbed into the skin, although it has not been determined if this absorption has any human health defects.

Although the FDA is partially funded through government taxes, the major source of funding is the exorbitant fees that they charge for FDA approval. So, the FDA is simultaneously protecting the best interests of the public as well as keeping Big Pharma and the major industry companies (which make and sell sunscreens) happy with their approval (or disapproval) of products. In such a scenario, there might be economic reasons to keep the status quo, and lesser ones to introduce new sunscreen products to market. Such a Sisyphean task is seen in other parts of our government. For example, the US Department of Agriculture is simultaneously charged with protecting the economic interests of American farmers and meat and dairy products as well as protecting the nutritional interest of Americans [7].

A partial list of specific needs for improved coverage of the public health of our citizens includes:

(1) Allow widespread usage and sales of both Mexoryl XL (lipid soluble) and Mexoryl SK (water soluble). These chemicals have broad sun protection in the UVA and UVB range. They are photostable with virtually no side effects. They have been sold in Europe, Japan, and Canada since 2000.

(2) Allow the distribution and sales of Tinosorb S (bemotrizinol), Tinosorb B (Bisoctrizole), and related chemicals, Tinosorb A2B (tris-biphenyl triazine) and Tinosorb OMC (octyl methoxycinnamate). They act by being a chemical as well as a reflective sunscreen. These chemicals are very photostable and block the entire range of UVA and UVB. They tend to increase the stability and effectiveness of other chemical sun fillers. They have been available in Europe since 2008.

(3) Allow the distribution and sale of Uvinul A plus (diethylamino hydroxybenzoyl hexyl benzoate), which is a stable form of avobenzone that absorbs all the way to 400 nm.

(4) Only allow "non-nanutized zinc oxide and/or titanium dioxide. This will allow the ingredients to be 100 nm or more in diameter and safer for organisms.

An example of these "new" sunscreens would be Omi's Verdio Sun Essence, a Japanese sunscreen that uses sun filters, octinoxate, uvinul A plus, tinosorb S, and octocycle, which provide broad-spectrum protection without leaving any kind of white cast behind. It retails at $9/tube at Stylevana, an Asian online shopping site.

CONCLUSION

Sunscreens have become the most popular means of sun protection against UV radiation in Western countries. Better UVB-UVA broad spectrum sunscreens exist in the world that are non-toxic and more effective. A better outcome of sunscreen efficacy can be achieved with the allowance of these products into the American market.

CONFLICT OF INTEREST

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