Sunscreen News, Views, and Miscues

What your patients—and you—should know about the latest developments around sunscreens.

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>> While it seems that sunscreens are perennial fodder for news outlets, the past few months have brought an extraordinary amount of coverage—some positive, some negative, and some downright inaccurate. Keeping tabs of the information being publicized can prepare us to address patients' concerns and perhaps offer some pre-emptive education to support healthy UV avoidance habits.

FDA MONOGRAPH UPDATE

In late February, the FDA issued a proposed rule that would update regulatory requirements for most sunscreen products in the US. The public comment period for the proposed rule ended late last month.

A key aspect of the proposal relates to the classification of sunscreen ingredients as generally recognized as safe and effective or GRASE. The agency says that of the 16 currently marketed active sunscreen ingredients, two ingredients—zinc oxide and titanium dioxide—are GRASE for use in sunscreens, while two ingredients—PABA and trolamine salicylate—are not GRASE for use in sunscreens. The remaining 12 ingredients have "insufficient safety data to make a positive GRASE determination at this time."

For some observers (and headline writers), this statement indicated that the sunscreen ingredients are not safe. However, this is not precisely what FDA is saying. In fact, those 12 ingredients will continue to be permitted in sunscreens.

It may be helpful to review what the GRASE designation means (See the sidebar for the FDA's description). When an OTC drug is deemed GRASE, then any products containing it can come into market without individual FDA evaluation and approval. Lack of GRASE designation does not preclude an OTC drug from being brought to market; it simply means the drug may require individual FDA review and approval in order to be legally marketed.

Other aspects of the proposed rule may have greater significance for patient care and long-term UV protection. For one, the FDA still is not proposing a standard rating for UVA protection that consumers can assess that would be analogous to the SPF rating for UBV protection. However, the agency is proposing that all sunscreens with SPF 15 or higher be required to be broad spectrum and that the magnitude of UVA protection must increase in proportion to the SPF. In other words, higher SPF sunscreens will offer greater UVA protection compared to lower SPF.

The Take-away for Patients: The FDA has not deemed commonly used chemical sunscreens unsafe and has not ordered them off the market. The agency is simply seeking additional information in order to simplify the path to bringing new products to market. The ingredients deemed unsafe—PABA and trolamine salicylate—had been largely abandoned in the US already.

Patients who remain concerned about sunscreen ingredient safety can rest assured that physical sunscreens—titanium dioxide and zinc oxide—are available and are deemed GRASE.

Patients should also be reminded of the importance of broad spectrum protection to protect against UVA as well as UVB, and of the need to practice other UV avoidance strategies, like covering up and avoiding mid-day sun.

SUNSCREENS LACK EFFICACY, ACCORDING TO EWG

The Environmental Working Group is out with its annual sunscreen review and ranking and once again the group suggests that many sunscreens do not provide the level of protection stated on the label. The group assessed more than 1,300 products with SPF, "and found that about two-thirds still offer inferior sun protection or contain concerning ingredients."

The EWG lobbies for changes to sunscreen manufacturing, testing, and marketing. The group has long favored physical sunscreens and is often cited as contributing to confusion about the effects and safety of chemical sunscreens. As such, many physician scientists are dismissive of the group.

And, in fact, it should be noted that their sunscreen rankings penalize products that "contain concerning ingredients."

However, there may be some useful information in the EWG analysis. On the one hand, since FDA regulates sunscreens, we should be able to assume any formulation on the market works as labeled. However, don't we ourselves sometimes argue that generics—also FDA regulated—do not perform to the level of innovator drugs? We must be honest that there probably are some sunscreen formulations on the market that underperform. Especially concerning is that EWG tests formulations under controlled conditions. When it comes to day-to-day use of sunscreen formulations, we know based on American Academy of Dermatology data that patients tend to use less sunscreen than indicated and reapply it less frequently than they should.

The Take-away for Patients: Dermatologists can advise patients that the EWG is somewhat controversial and the dermatology community does not fully endorse the group's claims. However, patients can look to the group's sunscreen ratings (Consumer's Union, publisher of *Consumer Reports* has also tested sunscreens) for guidance on product selection. The ranking (ewg.org/sunscreen/best-sunscreens) includes recommendations in multiple categories, features many mass-market brands, and even allows for search by cost.

Once again, patients should recognize that sunscreen is just one part of a UV avoidance strategy and must be reminded to apply sufficient product and to reapply as directed for optimal benefit.

SUNSCREENS IN THE BLOODSTREAM

According to results of a study published in the *Journal of the American Medical Association*, when healthy subjects applied sunscreen at the recommended dosage to 75 percent of their body surface area four times per day for four days, detectable levels of active ingredients in the sunscreen exceeded the threshold that the FDA established to waive some nonclinical toxicology studies. In fact, the limit was exceeded for all four tested formulations after four applications on day 1. (Read about the study and see physician reaction on p. 10)

Of note, the study required subjects to apply sunscreen as it is intended to be used, which means a substantial amount of sunscreen was applied. This is inconsistent with how most people actually use sunscreen—especially on a daily basis. Therefore, the average consumer will not have similar chemical exposure.

The Take-away for Patients: While this study identified sunscreen chemicals in the bloodstream, it was not designed to determine the consequences of such exposure. Rather, the study showed that these chemicals enter the bloodstream at levels that warrant toxicology studies. From the physician's standpoint, such studies could be valuable. If they document the safety of chemical sunscreens, we will have hard science to refute claims of sunscreen danger. If the findings are negative, then worrisome ingredients will be pulled from the market or monitored. Note that physical sunscreens have not been shown to enter the bloodstream.

Subjects in the study covered 75 percent of their body surface area. Patients who want to reduce their potential exposure to chemical sunscreen should be counseled on the need to use additional protective strategies in addition to sunscreens. UPF swim suits that cover the torso and a portion of the legs can reduce the need to apply sunscreen to these body areas.

SUNSCREENS AND CORAL

Hawaii and the town of Key West, FL have banned sunscreens containing oxybenzone and octinoxate, claiming that the chemical sunscreens damage coral and therefore pose a threat to marine life. The problem, however, is that data regarding the impact of the chemicals on sea coral are limited. While a study showed that application of these chemicals in test situations damaged coral, it has not been shown to what extent the chemicals actually reach and affect coral in actual use.

Environmentally conscious patients may abandon sunscreens for fear of harming the coral while others may misinterpret the ban as a sign that sunscreens are generally unsafe.

The Take-away for Patients: Once again, physical blockers present an alternative to chemicals for any patients who either cannot or choose not to use chemical sunscreens. Combined with other UV avoidance strategies, zinc oxide

What is GRASE?

Per FDA.gov, first, the particular drug product must have been subjected to adequate and well-controlled clinical investigations that establish the product as safe and effective.

Second, those investigations must have been published in the scientific literature available to qualified experts.

Third, experts must generally agree, based on those published studies, that the product is safe and effective for its intended uses. At a minimum, the general acceptance of a product as GRASE must be supported by the same quality and quantity of scientific and/or clinical data necessary to support the approval of a New Drug Application.

or titanium dioxide based products will protect swimmers with no apparent impact on the environment.

It may be helpful, however, to clarify for patients what we do and don't know about the effects of chemical sunscreens on coral. Importantly, even if oxybenzone and octinoxate harm coral, that does not indicate the chemicals are unsafe for humans and there's no reason they cannot be used at the pool, in the woods, or in other settings.

ONGOING DEVELOPMENTS

Arguably no other OTC drug class is as controversial as sunscreens. The reasons for skepticism and mistrust are not clear; we know that, unfortunately, the public may not consider skin cancer a serious health concern, which may be relevant.

Patients need continuous reminders to use broad spectrum sunscreen, to apply it properly and to reapply as needed, and to use other essential UV avoidance strategies in order to protect their skin. Sunscreen formulations can be a safe and important tool in preventing premature aging, skin damage, and skin cancer. Dermatologists should clarify issues related to sunscreen safety and efficacy so that patients are able to make the most appropriate choices for protection. ■