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## EDITORIAL

# The Important Role of Dermatologists in Public Education on Sunscreens

Tasneem F. Mohammad, MD; Henry W. Lim, MD

**The Sunscreen Innovation Act** was enacted on November 26, 2014, to help expedite the approval process for UV filters by the US Food and Drug Administration (FDA), given that no new filters had been approved in several



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years. Nearly 5 years later, on February 26, 2019, the FDA released a proposed rule (84 FR 6204)<sup>1,2</sup> in response to the Sunscreen Innovation Act that addressed the classification and labeling of over-the-counter sunscreen products. A component of this FDA proposal is to classify the 16 sunscreen active ingredients (ie, UV filters) listed in the 1999 FDA final monograph into 3 categories: category I, generally recognized as safe and effective (GRASE); category II, not GRASE; and category III, insufficient safety data to support a positive GRASE determination. Currently, sunscreen manufacturers are working with the FDA to discuss safety data needed for 8 of the 12 active ingredients listed in category III.

Another component of the FDA proposal is to require sunscreen active ingredients to be placed on the principal display panel of the label to facilitate product comparison.<sup>1,2</sup> The principal display panel is defined by the FDA as the portion of the label that is most evident when the product is displayed for retail sale. It should be noted that although changes to sunscreen labeling have been proposed, little is known regarding how consumers evaluate and prioritize sunscreen ingredients in their decision-making and selection of sunscreen products. Therefore, evidence is greatly needed to identify key points for dermatologists to better educate patients regarding sunscreen as a part of photoprotection.

In this issue of *JAMA Dermatology*, Tribby and colleagues<sup>3</sup> evaluate how the proposed revisions may affect labeling. The authors explore the usefulness of listing the active ingredients on the principal display panel and the ability of study participants to recall these ingredients when selecting sunscreen products. Study participants were shown 2 mock labels, 1 meeting the current FDA guideline and 1 aiming to meet the proposed FDA guideline. Participants were queried on the recall of ingredients and how the ingredients influenced their sunscreen selection. The study found that fewer than 30% of study participants used information on the active ingredients as the primary factor in choosing sunscreen and that only 11% could recall any of the active ingredients after viewing both labels.

Only 1 of the 47 participants in the study by Tribby and colleagues looked at the label to seek environmentally safe ingredients.<sup>3</sup> The main reason for environmental concern is the association found between the active ingredients in sunscreen and coral reef bleaching, with oxybenzone being the

most widely discussed UV filter.<sup>4,5</sup> In laboratory settings, the concentration of UV filters required to decrease chlorophyll content and overall coral cell growth is 1000-fold higher than that measured in ocean water. Also, it is not clear what relative contribution sunscreen-derived oxybenzone makes to marine environments, which may be detrimentally affected by industrial sources of oxybenzone as well as by global warming.

On January 1, 2021, Hawaii banned the sale of sunscreen products containing octinoxate and oxybenzone. On January 21, 2021, the state's legislature introduced new bills that propose also banning sunscreens containing avobenzone, homosalate, octisalate, and octocrylene.<sup>6</sup> However, because of the relatively small number of FDA-approved UV filters, their removal from the US market is not easily accomplished. There are limited options for achieving a final sunscreen product with a high sun protection factor (SPF) and broad-spectrum coverage. Approval of other broad-spectrum photostable filters by the FDA would be most beneficial to achieving this goal. Considering the varying degrees of environmental awareness and concerns in different geographic areas, if the study by Tribby and colleagues<sup>3</sup> had been conducted in an area other than Washington, DC, a higher percentage of participants might have tried to avoid ingredients with perceived environmental consequences.

Five of the 47 participants in the study by Tribby and colleagues<sup>3</sup> avoided certain ingredients for personal health reasons. A systematic review of 29 studies<sup>7</sup> was recently published on the association of octinoxate and oxybenzone with human health. For oxybenzone, no adverse effects were observed for male or female fertility, female reproductive hormone levels, adiposity, fetal growth, child neurodevelopment, or sexual maturation. While associations with thyroid hormone, testosterone level, kidney function, and pubertal timing were reported, causal relationships were not established. No reported effect of octinoxate on thyroid or reproductive hormone levels was noted. The authors concluded that current evidence is not sufficient to support the causal relationship between an elevated systemic level of octinoxate or oxybenzone and adverse health outcomes.

In a study by Matta and colleagues,<sup>8</sup> scientists at the FDA showed systemic absorption of 6 organic sunscreen filters when applied to 75% of the body at a concentration of 2 mg per cm<sup>2</sup> (the concentration used in SPF testing). Notably, absorption was detected even after a single application. This finding was used to support the need for additional safety testing on sunscreen filters; however, the authors clearly stated that their results did not indicate that individuals should refrain from using sunscreen.

As discussed by Tribby and colleagues,<sup>3</sup> a previous study by Xu and colleagues<sup>9</sup> showed that cosmetic elegance is the most-cited positive feature of highly rated sunscreens. This study focused on sun-sensitive individuals who typically have fair skin and may apply products containing inorganic filters (ie, titanium dioxide and zinc oxide) to maintain a cosmetically preferred appearance. In consumers with richly pigmented skin, sunscreen is used primarily to prevent photoaging and pigmentary problems. This subgroup may favor organic (also known as chemical) sunscreen filters because inorganic filters can be cosmetically unacceptable—leaving a white film on the skin. Further studies are needed on sunscreens and individuals with richly pigmented skin.

In the US, active ingredients in sunscreens are regulated by the FDA as over-the-counter drugs. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act<sup>10</sup> was signed into law. Under the CARES Act, the FDA is to update and finalize requirements for over-the-counter drugs, including sunscreens, via a streamlined administrative order process intended to improve efficiency, timeliness, and predictability. As a result, a final sunscreen order will no longer undergo a time-consuming 3-phase process to be incorporated into the final sunscreen monograph<sup>11</sup>; instead, it will automatically be deemed a final administrative order and be effective immediately. Consequently, the CARES Act will replace the Sunscreen Innovation Act on September 30, 2022.

Under the CARES Act,<sup>10</sup> the FDA is required to issue a proposed administrative order by September 27, 2021. Once the

final administrative order has been issued, sunscreen manufacturers will have at least 1 year to ensure that products offered on the shelves in the US are in compliance. The CARES Act also incentivizes innovation by providing an opportunity for an 18-month exclusivity period to the requesting manufacturer of a new filter. This exclusivity period begins on the date when the manufacturer can lawfully market the sunscreen ingredient. Notably, none of these provisions change the safety testing that the FDA is requiring for category III sunscreen ingredients listed in the 1999 proposed rule.<sup>1,2</sup>

The study by Tribby and colleagues<sup>3</sup> confirms what most clinicians have suspected from interacting with patients—that the general public may not have enough information on the key factors that should influence decision-making regarding sunscreen selection. While most consumers look for SPF values, and some might look for broad-spectrum labeling, this study points to an opportunity for dermatologists to educate patients on the key factors to consider when choosing a sunscreen.

Dermatologists are in the best position to educate the public on the importance of photoprotection for skin health, including seeking shade when outdoors; wearing photoprotective clothing, a wide-brimmed hat, and sunglasses; and applying broad-spectrum sunscreen with an SPF 30 or higher. Given the evolving information on sunscreen safety, the environmental consequences of sunscreen, and new sunscreen regulations, dermatologists are in a unique position to educate the public on the proper practice of photoprotection and to provide objective and updated information on sunscreens.

#### ARTICLE INFORMATION

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