

# FILTERING SOME RUMORS REGARDING SUNSCREENS

**R**UMORS abound that the Food and Drug Administration is poised to finalize the long-awaited sunscreen monograph, which is designed to regulate the sun protection that

consumers receive from sun care products. At the same time, the FDA has promised to finalize the approval of the Time and Extent Application (TEA) for several European ultraviolet filters. It is conceivable, though hard to imagine, that by the time you read this column, we could have new sunscreen regulations in the U.S.!

But in an industry rife with rumors, pinpointing the truth can be tricky. Modern methods of information dissemination

have altered the usual terrain; a unified voice is needed. Consumer opinion of U.S. sunscreen safety and regulations has been swayed. With the alarming rise of skin cancer, consumers are aware that current regulations are inadequate. Media and consumer group reports, as well as professional and laymen blogs, speak volumes about the damage that the lack of regulations has had on adequate protection, public misconception and even sun care commerce. This is compounded by the meteoric rise of blogs, emails and more importantly, the lack of adequate education by cosmetic companies and trade organizations. Traditionally, we looked to our governing bodies and organizations for the latest word on safety. But the latest discussions are unmonitored, led by independent groups whose dialogue has grown perplexing.

## Confusing Reports Surface

Numerous reports about avobenzene's photoinstability surfaced and the lack of adequate UVA protection in the U.S. took center stage. At the same time, there were reports about the endocrine-disrupting ability of UV filters, most notably octinoxate, along with a series of reports revealing that oxybenzone was found in 97% of Americans tested. Meanwhile there are more reports on the effect of sunscreens on vitamin D production, the purported damage of UV filters on coral reefs and UV filter residue in wastewater and marine life.

Of course, litigation against the five major sunscreen manufacturers and the lawsuits/countersuits between Schering-Plough and Neutrogena<sup>1</sup> did not help, nor did the raging controversy on the safety of nanoparticles, the American Academy of Dermatology seal, the safety of artificial tanning and the misuse and abuse of suspect terms and statements in describing sun care products and their functions. These terms

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include: chemical-free sunscreens, natural sunscreens, organic sunscreens, waterproof, all-day protection and blocks all harmful rays. The appearance of high SPF products (55 to 100) on the U.S. sun care market added to this confusion.

All of it is mind-boggling, especially to the unsuspecting, ill-informed consumer who reads both scientific reports and soccer mom blogs in the belief that all are reputable. Few resources for balanced information exist and mediating entities are sorely needed to address the controversies. In previous columns, I detailed the efforts of senators, congressmen and generals as well as cosmetics and consumer groups to affect change. In fact, the Sun Act was introduced in Congress on May 20, 2009, requiring the FDA to finalize the monograph in 180 days.<sup>2</sup> On May 14, 2009, Matthew Holman of the FDA declared that a final decision on the first five TEA UV filter applications will be issued this month.<sup>3</sup>

Yet, some independent voices ring out more loudly over the din. The Environmental Working Group (EWG) has produced many reports in the past few years and its website is visited more than a million times a month.<sup>4</sup> Yet, despite a mild challenge by The Council a few years back<sup>5</sup> and



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a more extensive response by The Council recently,<sup>6</sup> no one has produced any extensive scientific data that challenges EWG's findings. While I am impressed with EWG's efforts, the slamming of the mainstream cosmetic industry in favor of the so-called natural cosmetic industry generates alarmist conclusions rather than ones based on in-depth scientific studies. However, no one else has taken the time to evaluate all the sun care products (2,073) that are manufactured in the U.S.

The EWG has disseminated information concerning the lack of regulations, the inadequacy of some sun care products and the effect of UV filters on the environment. However, EWG must consider the impact that its studies have on the consumer. For instance, its reliance on mathematical models to assess UVA damage and photostability rather than actual testing (including recognized protocols of in-vivo and in-vitro tests that the FDA calls for and the sunscreen companies adhere to) is not helpful. Its final assessment and ranking of U.S. sunscreen products is arbitrary and is based on debatable issues that determine the effectiveness of sun care protection. The EWG recently changed its assessment of nanotechnology. In the past, the group questioned the use of UV filters made with nanoparticles but in its 2009 study, EWG cited several studies that found no nanoparticle penetration into the skin.<sup>7</sup> In this way, EWG contributed to the doubts that U.S. consumers have when choosing sun care products.

## Filters Are Not Benign

EWG and similar groups cite reports about allergies, photoallergies, endocrine disruption and chemical degradation of UV filters without considering the effect they may have on the unsuspecting public. Degradation studies of UV filters that occur in parts per million are sometimes cited without consideration as to the actual impact on safety, as opposed to their superior functionality. To be efficient absorbers of harmful rays, UV filters are active chemicals that must be aromatic molecules with multiple

chromophores. As such, they are not benign ingredients or "mild as water." A risk-benefit analysis must be conducted in each study and the real impact assessed carefully.

There is no gain without risk. For example, vitamins, artificial sweeteners and pharmaceuticals have side effects as well as benefits that con-



**Consumers think they're getting burned by their sun care products.**

tribute significantly to quality of life. Eliminating them at the first minor alarming study does not address the multitude of diseases and ailments confronting society today. Similarly, trashing potentially helpful UV filters does little to protect the consumer from the ravaging rays of the sun.

The EWG has cited statistics revealing that this year's batch of U.S. sun care products had a 2.4 fold increase in UVA protection over 2008. If that statistic is correct, that would be a most welcome development. From my experience, many individuals and companies are aware of EWG's Skin Deep program, and some are adhering to its recommendations. This is an impressive achievement in just a few short years. Now, the EWG should collaborate with mainstream companies, scientists and concerned organizations to truly improve sun protection. Collaborative insight and resources could result in superior

products that offer better overall protection to the consumer and help guide adequate governmental regulations.

The U.S. consumer has been battered by the lack of regulations, alarming medical statistics and controversial terms for products and ingredients alike. To address the rumors, a unified voice is needed. A dialogue between EWG and other consumer advocacy groups with the FDA, AAD, The Council, sun care companies, scientists, dermatologists, academicians and legislators will improve communications and ultimately benefit consumers, regulators and the sun care industry. Cooperation will help produce more complete regulations sooner and consumers will be better protected and more informed, science will be better and the industry will be more responsible and profitable. Let us work together to filter out the rumors about sunscreens.

## More on Tanning Salons

My March and May 2009 columns detailed the hazards of tanning salons. On July 29, 2009, the *Lancet Oncology*<sup>8</sup> published a report by the International Agency for Research on Cancer that tanning beds are "carcinogenic to humans." The Agency moved tanning beds and other sources of ultraviolet radiation into the top cancer category, deeming them as deadly as arsenic and mustard gas! A new analysis of about 20 studies concludes that the risk of skin cancer jumps by 75% when people start using tanning beds before the age of 30! ●

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