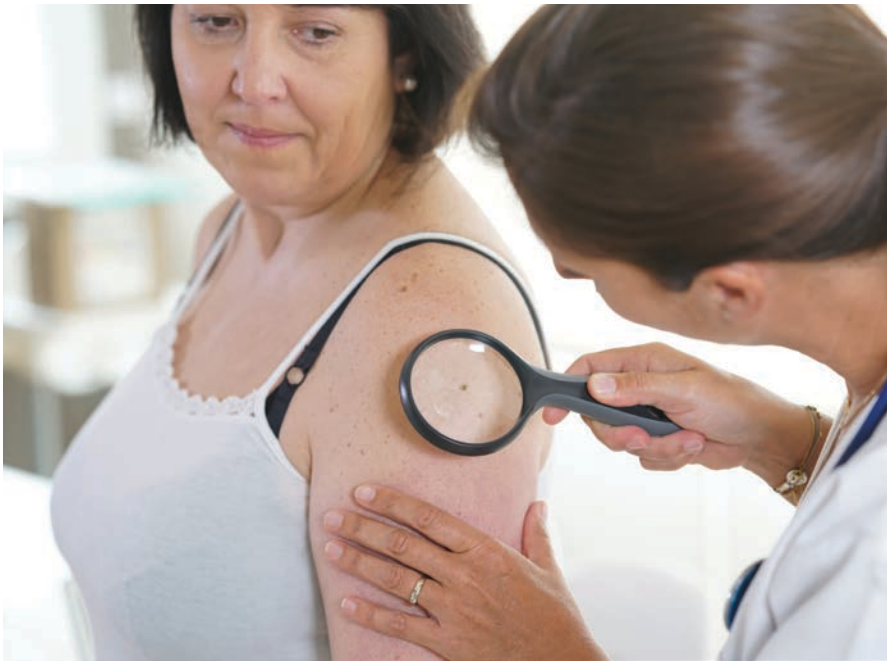
ARE THE ODDS STACKED AGAINST SUNSCREEN USE?

RECENT calls echo loud and clear against the safe, effective use of sunscreens to prevent skin cancer. They emanate from the four corners of the world and include the US Food and Drug Administration (FDA), environmentalists worldwide, and even toxicologists and researchers around the globe. Of course, the internet lights up whenever negative research about sunscreens surfaces; if you're on Facebook, Instagram or Twitter, or simply Google citations, these negative messages stare you right in the face from your computer screen.

Our cosmetic and sunscreen industry, and most dermatologists, have advocated the safe use of sunscreen products as one of the most important regimens for protection against skin cancer. Together with sun abstinence, use of protective clothing, hats, and umbrellas, sun care products have enjoyed a surge of consumer use with double-digit growth in worldwide sales for years. Many studies, such as those of Green, Hacker, Ghiasvand, Burd and others, have demonstrated the effectiveness of using sunscreen lotions and creams for protection and abating the risk of skin cancer due to overexposure. Unfortunately, skin cancer is still on the rise and has reached epidemic proportions—it still ranks as the single most prevalent cancer today. With nearly 3.5 million cases of skin cancer diagnosed annually in about 2.2 million patients in the US, including over 80,000 cases of deadly malignant melanomas, protection is paramount.



Most dermatologists understand the important role that sunscreen plays in preventing skin cancers.

Let me first enumerate the many citations and arguments of individuals, organizations and advocacy groups that have joined the chorus bemoaning the pitfalls of using sunscreens for cancer protection.

Starting from the top, the US FDA is largely responsible for the chaos and uncertainty that industry and consumers are experiencing today. Consider the statement made to Congressional aides by the FDA's Theresa Michele, the director of Nonprescription Drug Products (NPDP), that "not everyone can get skin cancer from the sun, but everyone can get skin cancer from sunscreens."

Imagine a 50-year-old thriving industry that has never ever had final regulations. Since the early 1970s, there have been calls for regulations in the field of sunscreens. An expert panel was convened and the first regulation, the Advanced Notice of Proposed Rulemaking (ANPR) was issued in August 1978. It listed 21 UV filters at specified ranges that would be deemed safe and effective to "prevent skin cancer." Fifteen years later, in 1993, the Tentative Final Monograph was issued; and nearly 15 years passed before the Proposed Final Rules were issued in August 2007. Finally, the Final Rule was issued in June 14, 2011 and was implemented in December 2012. But wait! That was not the Final Monograph but rather the Final Rule that only states that a sunscreen product must comply with the three following conditions:

1. A minimum of SPF 15

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2. A Broad Spectrum claim (Critical Wavelength)
3. A modified Principal Display Panel-Drug Facts.

No decision was made then (2011) on the eight pending Time and Extent Application (TEA) sunscreen ingredients. Also, no limit was set on SPF (hence the soaring and chaotic SPF numbers we see today), no decision was made on the safety of sprays, combinations with avobenzone, or a host of other issues. If a sunscreen product complies with the above three conditions, then cosmetic companies can now make the following "drug" claim: "Sunscreens reduce the risk of skin cancer and early skin aging when used as directed."

Blame FDA…

The use of this drug claim by the "eager" and "over anxious" sunscreen and cosmetic industry is the reason why the FDA treats regulations of sunscreens in the same vein as it treats a cancer treatment drug, a cholesterol-reducing drug, a blood pressure lowering drug or a heart failure treatment drug! How can a product, which presumably does not alter any biological function in the body, be treated as a drug and not just a cosmetic that simply reflects or absorbs harmful ultraviolet radiation? Most countries around the world consider sunscreens as cosmetics not drugs. In the US, drug approval is a drawn out, extensive and expensive proposition requiring millions of dollars and a half dozen years to complete all the elaborate testing and requirements to comply with drug standards established by the FDA.

Another consequence of treating sunscreens as drugs has been the restriction imposed by authorities in schools, camps, public pools and beaches requiring parental permission for using sunscreens on children. Fortunately, a few states (including Louisiana, Washington and Arizona) are currently passing legislation for the free use of sunscreens in schools and, in effect, distinguishing between sunscreens and other OTC drugs administered to children in the school.

Current regulations are destroying research efforts to find new UV filters.

…and the Industry!

Unfortunately, the second culprit in the chaotic sunscreen protection scene is the sun care industry itself. We shouldn't have touted our products as regimens to protect consumers from skin cancer. Rather, we should have been satisfied with claiming only that effective use of these products reflects or absorbs the solar radiation (mostly ultraviolet), the consequence of which may reduce the effects of exposure to the harmful rays of the sun.

The industry should be more engaged in education and advocate for the safe use of sunscreens. When false or negative information surfaces—whether unsubstantiated internet reports or substantiated medical, environmental or scientific studies—the industry should react and respond appropriately. These responses must come from individual companies as well as from advocacy groups, whose response to a host of negative issues that surfaced during the past decade have been dismal. Even the Personal Care Product Council rarely reacts and issues statements or convenes studies to refute those claims. The American Academy of Dermatology is better at responding to cancer and dermatological threats caused by sunscreens but it too, is not totally effective.

Other threats to the sun care industry that I have highlighted in previous columns have come from a multitude of sources and include the following claims:

1. Sunscreens decrease vitamin D levels.
2. Sunscreens destroy coral reefs.
3. Spray sunscreens are the new "second hand smoke."
4. Oxybenzone is an endocrine disruptor.
5. Sunscreens destroy oyster beds.
6. Half of the sunscreens tested had an SPF below their label SPF.
7. 40% of sunscreens did not adhere to AAD guidelines.
8. Sunscreens disrupt sperm cell function.

Well, you get the picture.

Sunscreens are under attack. Their efficacy and safety are being questioned. Skin cancer is on the rise. Disastrous tanning booths are still frequented. Regulations are still not forthcoming. Basic research on new effective ultraviolet filters has been virtually eliminated in the US. Who will spend considerable time and money on research that can never be implemented and eventually commercialized? What can be done? What should be done?

I have many thoughts and ideas. Please email me with suggestions and plans to reverse this negative trend. Sunscreen use may not be a panacea, but certainly, when used effectively and appropriately, it should be our first line of defense against the ravaging rays of the sun. I will share my thoughts and yours in my next column entitled "The Case for Using Sunscreens." ●