

SPF GOES TO COURT!

SUNSCREENS have been in the headlines recently. We start the New Year with an act of Congress, The Sunscreen Innovation Act (SIA), which was just signed by President Obama into law in November. Its implications will be debated extensively in the future until the FDA goes about finalizing and, hopefully, ultimately approving the TEA (Time and Extent Applications) pending for the past dozen years or so. In the meantime, other recent and new developments in sunscreens and the sun care industry have gone unnoticed. This column will briefly address a few of those developments.

On Nov. 25, 2014, a very important class action lawsuit was dismissed in California State Court. In *Gisvold v Merck* (S.D. Cal.) a class action lawsuit alleged that consumers have learned to associate higher SPF values with superior sun protection but that products labeled with high SPF values were misleading, since sunscreens with SPF values greater than 50 allegedly do not provide any increased clinical benefit over sunscreens with an SPF value equal to 50. The plaintiff

asserted that labels with SPF 50+, 70+, 80 and 100+ were false, misleading and reasonably likely to deceive the public under California's Unfair Competition Law and breach of express warranty theories.¹ The class action lawsuit sought damages and conjunctive relief, including that an order be issued requiring manufacturers to add a disclaimer on the label about the supposed lack of clinical benefit from high SPF sunscreens.

In a landmark ruling last summer, the US Supreme Court's decision to side with the plaintiff in *Pom Wonderful Inc. v The Coca Cola Company* (US, 134.S.Ct.2228(2014)), caused many to fear the decision would produce a wave of class action lawsuits challenging food, drug and cosmetic labels—even those that complied with FDA law on false advertising theories.² In the *Merck* (owner of Coppertone at the time— since then, sold to Bayer) case, the US District Court for the Southern District of California dismissed the proposed putative class action on primary jurisdiction and pre-emption grounds. I will attempt to explain those legal terms as they are of significance for all practitioners in the field of sunscreens. The court cited *Pom Wonderful*, but in this instance found that the Food, Drug and Cosmetic Act (FDCA) included an express preempting status that was “unambiguous and broad in scope.” The court found that the plaintiff's (*Danika Gisvold*) claim were pre-empted by the FDCA, which governs over-the-counter drugs like sunscreens. It states that, “no state....may establish or continue in effect any requirements that is related to regulation of [OTC drugs]; and that is different from or in addition to, or that is otherwise not identical with a requirement under the [FDCA].”³

The court dismissed the class action lawsuit for two reasons. The first reason is that the proposed label disclaimer about

the effectiveness of high SPF sunscreens would “plainly add to and is not identical” with the FDA's requirements, [and thus] is expressly preempted. The second reason the court dismissed the action was on primary jurisdiction grounds, because the subject of whether high SPF sunscreens provide additional clinical benefits is an issue that is currently pending before the FDA.⁴

The take-away lesson from this case is that unless (and until) the FDA finalizes its Final Rule on Sunscreens, most issues are debatable and lawsuit or class actions will not likely prevail. Settling the high SPF issue is one of many that the FDA has not yet addressed. Others include the final status of the TEA ingredients, the final list of Category I ingredients, the use and safety of spray products, the approval of the use of zinc oxide and titanium dioxide in combinations with avobenzone, and a host of other issues that govern the use, testing, safety and legal requirements of sunscreens.

Recent Developments

A review published in *JAMA Dermatology* in January 2014 showed that the UV exposure to UV wavelengths associated with indoor tanning beds account for nearly twice as many skin cancer diagnoses (400,000 cases) as smoking (200,000 cases). The review found that even just one tanning bed session increases the risk of getting melanoma, the deadliest form of cancer, by 75% in the US.⁵ Martina Sanlorenzo, MD at the University of California, San Francisco, Dept. of Dermatology, in a December 2014 publication at *JAMA Dermatology*, also reported in a publication entitled “The risk of melanoma in pilots and cabin crew UV measurements in flying airplanes” purports that pilots flying for one hour only at 30,000 feet get the same amount of radiation as that from a 20



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minute exposure in a tanning bed!⁶

Studies continue to be published on the appearance of sunscreens and cosmetic ingredients in coastal waters. In PLOS One, Antonio Tovar-Sanchez published “Sunscreen Products as Emerging Pollutants to Coastal Waters” has identified many sunscreens and cosmetic ingredients in coastal waters.⁷ In addition, a publication in the Journal of Environmental Research, co-authored by Dr. Sally Gow et al. from the Antarctica New Zealand Institute at the University of Canterbury, cited emerging organic contaminants (EOC) from sunscreens and cosmetics appearing in Antarctic waters.⁸

Citing an NIH study and the Department of Health’s Wadsworth Center in New York on the subject of infertility in men,⁹ Advanced Reproductive Care, Inc. (ARC), the largest network of fertility specialists in the US, advises men with fertility issues to be careful using sunscreens. This study reported that 30 benzophenone type chemicals may cause infertility in men. Fortunately, Dr. Adamson of ARC also stated that “by no means should sunscreens be avoided” He did add, however, that “for people hoping to have a child, avoiding these chemicals is something that should be considered.”¹⁰

Among the recent developments of the SIA has been the FDA announcing the availability of letters containing the FDA’s initial determinations and feedback on safety and effectiveness data submitted to demonstrate that certain active ingredients are generally recognized as safe and effective (GRASE) and not misbranded for use in over-the-counter (OTC) sunscreen drug products.¹¹ This specific reference to the pending Time and Extent Application (TEA) and the action taken was specifically issued to comply with the many provisions and deadlines imposed by the SIA. The FDA also set February 6, 2015 for a meeting with representatives of the PASS Coalition (Public Access to Sunscreens), the Consumer Healthcare Products Association (CHPA), Environmental



Sun protection is a topic of conversation on the beach and in the courts.

Working Group (EWG), Personal Care Product Council (PCPC) and other interested parties to describe the FDA’s interpretation of the statutes of the SIA.

Since February 2008, when the first issue of the Sunscreen Filter column was published, many of the sunscreen issues I wrote about then are still with us today and, unfortunately, do not seem to be headed toward a resolution anytime soon. While these standing issues are ongoing, the Sunscreen Filter will continue to present relevant analysis of all issues in sun care. Readers of my column, hopefully, will get a sense of the pulse and the heartbeat of the sunscreen industry. I will continue to report on the developments of the SIA and discuss its implication on our industry, which will also include the role of the FDA and its actions as it relates both to the SIA and the pending Final Rule. I will also address sensitive issues as lawsuits and legal actions since they bear heavily on the development of sunscreens in our industry.

Finally, I will cover and analyze new scientific developments, report the findings and research in sun care, ultraviolet filters, and methods of protection as well as their medical implications in

developing or curing cancer. The goal of The Sunscreen Filter, as always, is to keep you up to date on this multibillion dollar industry. ●

References:

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