# IN THE SUN, IN THE DARK





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Dr. Nadim Shaath is the president of

Alpha Research & Development Ltd., a consulting firm in White Plains, NY, specializing in sunscreen formulations and new product ideas in cosmetics, essential oils and ultraviolet filters. He has over 30 years of experience as chairman of the chemistry department at SUNY-Purchase, the technical director at Felton, the president of Nickstadt-Moeller, Inc. and the CEO of Kato Worldwide. He can be reached at *alphamd@aol.com*  RE WE ENCOURAGING a false sense of security among consumers? When we use sunscreens for protection, are we truly covered? Are we in the dark when we are in the sun?

In the upcoming installments of THE SUNSCREEN FILTER, I will attempt to shed some light on these questions. I have been collaborating with two prominent scientists, namely Dr. Steven Q. Wang, M.D., director of dermatologic surgery and dermatology, Memorial Sloan-Kettering Cancer Center, and Dr. Olga Dueva-Koganov, vice president of R&D, Integrated Botanical Technologies. Their recent work is especially relevant to our topic.

It has been estimated that in 2009, nearly 69,000 individuals were diagnosed with skin cancer in the U.S. That year,

nearly 9,000 people in this country died due to melanoma. As more people develop melanoma, we are faced with the reality that sun exposure has consequences that sun care products alone cannot address. Last month, Dr. Wang published an informative and useful book with The Johns Hopkins University Press entitled *Beating Melanoma: A Five Step Survival Guide.*<sup>1</sup> The book is timely since incidences of melanoma have risen dramatically during the past 50 years.

In his book, Dr. Wang details melanoma's profound effect on a patient on many levels: physically, psychologically, emotionally and economically. When first diagnosed with melanoma, patients react with a range of emotions from surprise, denial, frustration and confusion to fear and



Steven Q. Wang's new book debuted earlier this year. It is available from The Johns Hopkins University Press.

even despair. Many patients say that they feel themselves losing control as soon as this process starts. Dr. Wang addresses this range of emotions when he writes, "There is no doubt that you will go through an intense and stressful period from the time of diagnosis to the time when you complete treatment."

In the book, Dr. Wang addresses two phases of concerns faced by the patient. In the first phase, a period referred to as the "mad rush," many patients must quickly learn about the disease, seek experts near their home, and decide on treatment options. Patients agree that this is a highly stressful time. When they finally start treatment, many people described the process as chaotic and that they have lost control over their lives. After a successful transition through this phase, many people with melanoma feel a transient relief.

### Long-Term Concerns

At some point after treatment, however, most people who have had melanoma grapple with a fresh wave of questions and nagging concerns. They enter the second phase, the "marathon" period. They wonder if they will develop new melanoma or get other skin cancers. They wonder whether they need more treatments. They worry that their children and their siblings will get skin cancer too. The remaining chapters deal with networking and the checklist for beating melanoma. The book is a must read for anyone diagnosed with skin cancer and all practitioners in their field.

U.S. sunscreen trends lean toward the highest possible SPF protection, yet we may question whether higher SPFs actually result in greater protection. There is also an on-going debate if an SPF 100 sunscreen is needed. The answer may depend on how much sunscreen you apply.

"Most people apply 25 to 50% of the amount of sunscreen used to determine SPF," according to James M. Spencer, MD, of Mount Sinai School of Medicine. "Go easy on an SPF 100, and you're still left with an SPF of about 30."<sup>2</sup>

Dr. Olga Dueva-Koganov has been one of the leading scientists defining and refining in-vitro sunscreen testing in the U.S., especially as it pertains to photostability and UVA testing. She has published more than 60 scientific articles and has 20 patents/ patent applications. Her two recent articles on in-vitro testing address the challenges associated with facing the FDA proposed testing protocols<sup>3</sup> and also high SPF products in the U.S.<sup>4</sup>

UVB and UVA portions of sunlight gen-

erate different biologic end-points in vivo. Erythema is used for the determination of SPF factor (UVB protection). Persistent pigment darkening (PPD) is used for testing UVA-PF (UVA protection). Almost four years ago, the FDA published a proposed rule that included testing of sunscreen efficacy in vivo (SPF and UVA-PF) and in vitro (UVAI/UV ratio after pre-irradiation). The FDA proposed a Star system (0-4 Stars) to assess the amount of UVAI protection to complement the SPF and UVA-PF in vivo ratings and to ensure balanced and photostable UVA/UVB protection.<sup>5</sup>

While awaiting the FDA's final ruling, the U.S. sunscreen industry has responded to the perceived consumer desire by launching eight SPF 100+ products in 2010 and almost doubling this amount at the beginning of 2011. Dr. Dueva-Koganov evaluated UVAI/UV ratios of all 15 commercially available SPF 100+ sunscreen products (nine lotions and six sprays) introduced to the market in 2010 and at the beginning of 2011 according to the FDA proposed methodology<sup>5</sup> with one modificationusing Vitro Skin (N-19)6 as a suitable alternative substrate<sup>3</sup> instead of roughened quartz plates. A pre-irradiation dose was delivered by Solar Simulator 16S-300-002 (Air Mass 1.5) with XPS 400, a precision current source; and PMA2100 Radiometer with PMA2101 Detector (all from SolarLight Company, PA).7 Diffuse transmittance/absorbance measurements were conducted on Labsphere UV 2000S and Version 1.2 software was employed to calculate the UVAI/UV ratio.8 Descriptions of the test products, their absorbance spectra and respective UVAI/UV ratios after pre-irradiation are presented in the table on p. 78.

Sunscreen manufacturers developed products with the highest SPF 100+ values by utilizing FDA approved actives in optimized delivery systems in conjunction with photostabilizing/SPF boosting technologies, film-forming polymers, antioxidants, plantderived ingredients, and particulates (silica, modified silica) that help to improve product efficacy.<sup>4</sup>

Experimental data show that UVAI/UV ratios of SPF 100+ sunscreen products

launched in the U.S. in 2010-2011 can not achieve four-star ratings. They fall in the narrow range of 0.80-0.85 and belong to the proposed "High UVA Protection" category (Three Stars) while failing to fulfill the "Highest UVA Protection" criterion (Four Stars). There was no increase in UVAI/UV ratios of the SPF 100+ products launched in 2011 versus products launched in 2010.<sup>10</sup> This indicates that the highest UVAI/UV ratio or Four Stars, for sunscreens with SPF 100+ cannot be achieved with the use of sunscreen actives currently approved in the U.S. Approval of a new sunscreen monograph and new UV filters are expected from the FDA sometime in 2011, we've been told. The FDA's ruling and approval will provide the sunscreen industry with finalized in vitro testing methodology and new sunscreen actives that will enable the development of ul-

Product	Name	UVAI/UV Ratio
А	Neutrogena Spectrum+ Advanced Sunblock Lotion SPF 100+ Helioplex 360 full spectrum UVA/UVB Waterproof	0.83
В	Neutrogena Spectrum+ Face Advanced Sunblock Lotion SPF 100+ Helioplex 360 full spectrum UVA UVB Waterproof	0.84
с	Neutrogena AgeShield Face Sunblock Lotion SPF 110 Helioplex broad spectrum UVA/UVB Waterproof	0.80
D	Neutrogena UltraSheer Dry-Touch Sunblock SPF 100+ Helioplex Broad spectrum UVA/UVB Waterproof	0.82
E	Aveeno Active Naturals Continuous Protection Sunblock Lotion SPF 100+ Face active photobarrier complex Broad UVA/UVB protection Waterproof	0.84
F	Neutrogena Ultimate Sport Sunblock Spray SPF 100+ Helioplex broad spectrum UVA/UVB Waterproof	0.81
G	Coppertone ultraguard Sunscreen Lotion SPF 100+ Broad Spectrum UVA/UVB Protection Photostable Waterproof	0.82
н	Banana Boat Sport Performance ActiveMAX Protect Broad Spectrum Sunscreen—SPF 100 AvoTriplex Very Water Resistant	0.85
I	BB Sport Performance Active Max Protect Continuous Spray SPFUVB 110 High UVA Very Water/Sweat Resistant	0.81
J	CVS Ultra Dry Sheer Lotion Sunscreen SPF 100+ Solatec Photostable UVA/UVB protection—Water Resistant	0.82
к	CVS Fast Cover Continuous Clear Sport Spray SPF 100 Solatec Photostable UVA/UVB protection Water and Sweat Resistant	0.80
L	Neutrogena Ultra Sheer Body Mist Sunblock SPF 100+ Helioplex broad spectrum uva uvb waterproof	0.81
м	Coppertone Sport Clear Continuous Spray SPF 100+ Very Sweat Resistant Broad Spectrum UVA/UVB Protection	0.84
N	Neutrogena Spectrum+ Advanced Sunblock Spray SPF 100+ Helioplex 360 full spectrum UVA/UVB - Waterproof Sweatproof	0.82
0	Coppertone Sport High Performance Broad Spectrum UVA/UVB Sunscreen SPF 100+ Ultra Sweatproof Waterproof	0.82
*Products A-H were launched in 2010 and Products I-O were launched in 2011.		

## UVAI/UV Ratios of Commercially Available SPF 100+ Products\*

timate sunscreen products with SPF 100+ and higher UVAI/UV ratios.

Until an effective list of active ingredients is established and methodological standards are set, more independent research and analysis is necessary. Many dedicated individuals have been working on these issues. A recent book published by the Royal Society of Chemistry, which I have assisted in editing, is a must read for anyone working in the field of sunscreens and photoprotection. This themed issue on topical and systemic photoprotection includes 25 chapters published by the top scientists and institutions worldwide. It deals with topics ranging from protection and sun damage to testing, safety, photostability, UVA issues and ultra violet filter reviews.9

Consumers may not be as protected as they imagine. The highest level of SPF available in the U.S. does not provide the highest level of protection. Does the sun care industry suffer from exaggerated claims or overly rigorous standards? Currently, it appears unnecessarily difficult to provide the highest quality products and clearly communicate their capabilities and limitations. Until the FDA approves updated ingredients and regulates standards, we are all in the dark.

#### References:

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