A Message From the President

2011 has been an extraordinary year for melanoma treatments, with the introduction of not one but two new life-extending melanoma drugs. In March, as reported in the Spring 2011 issue of *Sun & Skin News*, the US Food and Drug Administration (FDA) approved Yervoy™ (ipilimumab), the first new melanoma drug in 13 years. The availability of any new treatment for melanoma, which will cause an estimated 8,790 deaths in the US this year alone, is exciting. But Yervoy™ has garnered particular enthusiasm: it is the first therapy proven to extend *overall survival* for patients with advanced disease. Many patients treated with Yervoy™ may have a two-year survival advantage, and a smaller percentage may be virtually cured.

While these treatments give us cause for great optimism, skin cancer is still an epidemic, and these new melanoma drugs are just one part of the solution.

In August, the FDA announced that another new melanoma drug had been approved. Like Yervoy™, Zelboraf™ (a.k.a. vemurafenib, or PLX 4032) represents an important breakthrough. The first targeted genetic therapy for melanoma approved to date, Zelboraf™ holds promise for patients whose tumors contain a specific gene mutation (defect) present in about 40-60 percent of melanomas. This issue of *Sun & Skin News* discusses the innovative treatment.

While these treatments give us cause for great optimism, skin cancer is still an epidemic, and these new melanoma drugs are just one part of the solution. Prevention is also essential, and you can make a difference in the fight against skin cancer simply by consistently practicing sun protection behaviors year-round — not just during the summer months or while you're on vacation. Now that fall is here, you should continue to protect your skin by seeking the shade, dressing in clothes that shield your skin from the sun, using sunscreen, and avoiding ultraviolet (UV) radiation tanning. For more information on protecting yourself, please visit our Prevention Guidelines: http://www.skincancer.org/Guidelines/.

Publisher and President: Perry Robins, MD
Executive Director: Mary Stine
Medical Editors: Ritu Saini, MD, Steven Q. Wang, MD
Executive Editor: Mark Teich *(mteich@skincancer.org)*
Managing Editor: Paul Melia
Associate Editor: Elizabeth Michaelson
Graphics Coordinator: Elena Gaillard

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Ask the Expert

Ronald Siegle, MD

Q. Are sunscreens safe? I have heard that their ingredients can cause cancer.

A. It is important to ask questions about the safety of products we use regularly, especially since some have been found to have a negative effect on our health. Fortunately, we have research scientists who work to find answers to our questions.

The best, most trustworthy answers to questions about sunscreen safety are based on a review of the newest information that has been both peer-reviewed (evaluated by experts in the field) and published in respected scientific journals. The "worst" answers come from individuals or special interest groups who may have a pertinent question but whose theories are untested or, if tested, unsubstantiated by other studies. This is what some people might call "junk science," and what some media outlets might call good stories for a slow news day! Let's look at three of the most commonly questioned sunscreen components.

Q. Can the UV filter oxybenzone cause cancer?

"Junk Science" answer: An old research study on rodents suggested that oxybenzone can penetrate the skin and produce free radicals, harmful substances that, in theory, may contribute to the development of melanoma, the deadliest form of skin cancer.

Best answer: Oxybenzone underwent extensive review and was approved by the FDA for its current use in sunscreens. It has been available in the US for more than 20 years and there is no evidence that it has any serious side effects in humans. Research on human subjects provides the most relevant and useful information about the safety of substances. We can't automatically assume that research findings on rodents are relevant in humans.

Q. Does retinyl palmitate speed the growth of tumors after sun exposure?

"Junk science" answer: A special interest group says an FDA study on mice done 10 years ago suggests that retinyl palmitate may speed the growth of tumors. The study was never published.

Best answer: Retinyl palmitate is the form of vitamin A that is stored by the skin. There is no evidence that vitamin A is carcinogenic in humans. In fact, vitamin A compounds (retinoids) actually help *prevent* skin cancer, eliminate skin precancers, and help reverse the aging effects of sun damage.

The mouse study has not been published in a peer-reviewed journal, which suggests that its findings were not deemed worthy of publication.

Q. Are nanoparticles (tiny, or "micronized"-sized particles) in sunscreen absorbed by the skin, and are they harmful?

"Junk science" answer: In theory, the small size of these particles could allow penetration through the skin, where the particles could gain access to DNA, causing skin cell mutations that can lead to cancer.

Best answer: Sunscreen is applied to the top layer of skin, made up of dead cells, and multiple studies have shown that nanoparticles do not penetrate living skin. The general consensus is that they pose no risk to human health.

Dermatologists know that one in three Caucasians will get skin cancer during their lifetime. Data clearly show that sunscreens help prevent skin cancer. For more information on minimizing your risk of skin cancer and sun damage, please visit http://www.skincancer.org/Guidelines/.

Our guest expert for this issue, Ronald Siegle, MD, is a dermatologic surgeon. He is Clinical Professor of Dermatology and Otolaryngology at The Ohio State University and in private practice in Columbus. He received his dermatology training at the University of Michigan and his surgical fellowship at Duke University. He also holds a Master's of Science degree in Human Nutrition from Columbia University. He is the author of a surgical textbook and numerous articles.

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Perry Robins, MD, President | Mary Stine, Executive Director

Breakthrough Melanoma Drug Approved — First in a New Class Of "Targeted" Treatments

The US Food and Drug Administration (FDA) has approved a new drug — the first of its kind — for the treatment of inoperable or advanced metastatic (spreading) melanoma. Melanoma is the deadliest form of skin cancer. The drug, called Zelboraf™, was found to delay disease progression and extend life significantly.

Zelboraf™ was successful in shrinking the tumors of 81 percent of patients who had the gene defect, the greatest response rate a melanoma drug has ever had.

Zelboraf™ (a.k.a. vemurafenib, or PLX 4032) is the first targeted genetic therapy approved for melanoma, meaning it is appropriate for patients whose melanoma tumors have a particular gene defect. Zelboraf™ blocks the function of the defective V600E BRAF gene, which is present in about

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40-60 percent of melanomas. Zelboraf™ slows or stops the uncontrolled (cancerous) cell growth associated with the gene defect. The drug was approved by the FDA's priority review program, which "fast tracks" reviews of drugs that may provide significant treatment advances.

In an early clinical trial, Zelboraf™ was successful in shrinking the tumors of 81 percent of patients who had the gene defect (or mutation), the greatest response rate a melanoma drug has ever had. In more recent trials of melanoma patients, all of whom had the mutated gene, those who received Zelboraf™ were 56 percent less likely to die in the study period than those who received standard chemotherapy. Average overall survival for patients receiving Zelboraf™ could not be determined because so many patients remained alive; in contrast, average survival for patients on chemotherapy was only 7.9 months. Patients on Zelboraf™ were also 74 percent less likely to see their disease advance compared with patients on chemotherapy.

Along with Zelboraf™, the FDA approved a test which determines if a patient has the gene defect and is eligible for the treatment. Zelboraf™ is taken orally, and the prescribed dose is 960 mg twice a day. The drug is marketed by Roche's Genentech division.

From Our Editors: In our Spring 2011 issue, the "Ask the Expert" column focused on when to remove "strange-looking" (atypical) moles. We have received a number of comments from physicians on the column (written by Cheryl Katcher, MD), expressing the belief that Dr. Karcher advised removing too many moles. Dr. Karcher recommended an aggressive approach, to prevent such moles from evolving into dangerous melanomas. Dermatologists are trained at different universities, which favor different treatment approaches, some more aggressive than others. As Dr. Karcher herself explained in her column, "another dermatologist might decide to remove" fewer moles, "and there is no hard and fast rule about this." In dermatology, as in other fields of medicine, every patient's case must stand on its own; each patient should consult with his or her own dermatologist to decide when a more aggressive or more conservative approach is warranted.

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More Evidence that UV Tanning Is Addictive

Researchers Find It Stimulates the Brain's "Rewards Center"

Exposure to ultraviolet (UV) radiation from tanning machines stimulates the "rewards center" in the brains of frequent UV tanners, which could cause tanning addiction, according to a new study in *Addiction Biology*. When activated, the rewards center releases feel-good chemicals, which "could reinforce the tanning behavior, encouraging excessive tanning," said Heidi T. Jacobe, MD, study coauthor and Assistant Professor of Dermatology at the University of Texas Southwestern Medical Center at Dallas.

Researchers studied seven volunteers, all of whom tanned indoors two to three times a week and reported some signs of UV light addiction, such as having difficulty limiting their tanning. During two 10-minute sessions, volunteers lay beneath a tanning canopy, receiving either real UV or "sham" UV (light emitted by a tanning lamp, from which the actual UV radiation had been filtered out). Each subject received one real and one "sham" UV session, and immediately after each, subjects applied a self-tanner to help prevent them from determining if they had had an actual UV tanning session.

"Subjects did not know whether they were exposed to real or 'sham' UV tanning rays, yet reported greater satisfaction and decreased desire to tan only when they were exposed to the real UV tanning rays," Jacobe said. "This implies a biological effect of tanning rays on the brain." This was supported by follow-up brain imaging studies in the same patients — subjects were injected with a solution that allowed researchers to identify telltale signs of rewards center activity (increased blood flow in specific areas of the brain) in a scan conducted 90 minutes after each tanning session. The real UV radiation activated the rewards center more significantly than the sham UV, prompting feelings of well-being — and possibly more UV tanning later. The data reinforced earlier research showing that UV triggers the body's release of opioid-like endorphins, chemicals that relieve pain and generate pleasurable feelings.

Both before and immediately after the tanning session, before they could see their skin color, subjects were asked about their desire to tan. The regular tanners exposed to real UV light all reported a marked decrease in the desire to tan.

UV radiation is associated with about 90 percent of all skin cancers. Indoor tanners increase their risk of melanoma, the deadliest form of skin cancer, by 74 percent. They are also 2.5 times more likely to develop squamous cell carcinoma and 1.5 times more likely to develop basal cell carcinoma.

More stories, news and information available at **www.SkinCancer.org**

State Tanning Law Update

California Enacts Nation's Strictest Teen Tanning Law

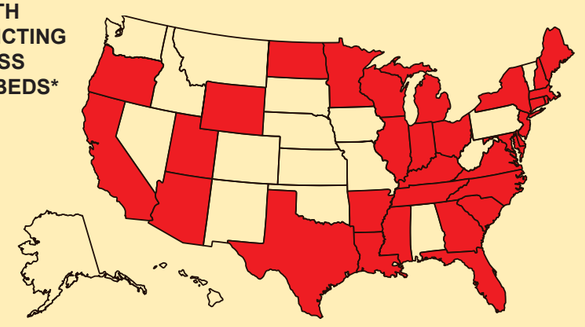
Children under the age of 18 have been banned from indoor ultraviolet (UV) tanning in California. On October 9, Governor Jerry Brown signed the bill replacing the Filante Tanning Facility Act of 1988, which allowed minors aged 14 and older to tan with the permission of a parent or guardian. Senator Ted W. Lieu proposed what has become the nation's strictest tanning law. It will go into effect in January, 2012.

Close to 2.5 million teens tan indoors in the US every year, increasing their risk of developing melanoma by 75 percent. Indoor tanners are also 2.5 times more likely to develop squamous cell carcinoma, and 1.5 times more likely to develop basal cell carcinoma.

According to the National Conference of State Legislatures,* some 32 states limit minors' access to tanning beds; many have statutes similar to California's Filante Act. Currently, Texas has the strictest teen tanning law: children under the age of 16.5 are not permitted to tan indoors, and older minors must have the written consent of a parent or guardian.

STATES WITH LAWS RESTRICTING TEENS' ACCESS TO TANNING BEDS*

AR	ME	OH
AZ	MD	OR
CA	MA	RI
CT	MI	SC
DE	MN	TN
FL	MS	TX
GA	NH	UT
IL	NJ	VA
IN	NY	WI
KY	NC	WY
LA	ND	



** As of Oct. 2011* (Source: http://www.ncsl.org/default.aspx?tabid=14394)