

Melanoma Research Alliance

August 1, 2013

RE: Docket **FDA-2013-N-0461**

Submitted via www.regulations.gov

Dear Members of the FDA General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee:

On behalf of the Melanoma Research Alliance (MRA), thank you for the opportunity to provide comments on the proposed order to reclassify sunlamp products as published in the *Federal Register* on May 9, 2013. The MRA supports the Food and Drug Administration's (FDA) proposal to reclassify these devices and to place additional restrictions on indoor tanning. This is an important first step to protect the public from the dangers of their use, and MRA urges the FDA to institute additional regulations to completely restrict minors under the age of 18 from the use and purchase of tanning devices.

MRA is a public charity that accelerates the pace of scientific discovery and its translation in order to eliminate suffering and death due to melanoma. To date, MRA has awarded more than \$48 million to 116 innovative research programs worldwide aiming to improve melanoma prevention, diagnosis, and treatment.

The use of indoor tanning devices is a known and significant health threat, especially to young people, as they are clearly associated with increased risk for all skin cancers including deadly melanoma. Melanoma is one of the most common cancers in the U.S., and the incidence is rising even at a time when incidence of other common cancers has declined.¹ Melanoma has the ability to spread widely to other parts of the body, and patients with disseminated Stage IV melanoma have a median life expectancy of less than one year. In 2013, more than 76,000 Americans will be diagnosed with melanoma – one every eight minutes – and more than 9,100 will die of the disease – one every hour. Melanoma is the second most common form of cancer for young people 15-29 years old. According to the National Cancer Institute, the estimated total cost associated with the treatment of melanoma in 2010 was \$2.37 billion in the United States.

Sadly, many melanomas could be prevented simply by reducing exposure to UV radiation, the leading environmental factor in the development of skin cancer. On its own website, the FDA warns consumers that UV radiation in tanning devices poses "serious health risks," including skin cancer.^{2,3} The world's leading scientific authority on carcinogens – the International

¹ Edwards et al. Annual report to the nation on the status of cancer, 1975-2006. *Cancer*, 2010 Feb 1;116(3): 544-73.

² Radiation emitting products: Tanning. *The U.S. Food and Drug Administration*. Retrieved August 1, 2013, from <http://www.fda.gov>.

Agency for Research on Cancer – has classified tanning devices in the highest cancer risk category: “carcinogenic to humans.” They established a 75% increased risk of melanoma in indoor tanning bed use before age 35, and a 225% increased risk of squamous cell carcinoma associated with “ever use” of indoor tanning.⁴ Subsequent research studies have confirmed the link between tanning beds and increased risk for melanoma and other skin cancers⁵ and have shown this risk increases with number of sessions or total hours of use.^{6,7} At the molecular level, UV radiation is known to damage the DNA of cells, and research has revealed that genomes of melanoma tumors are riddled with the type of DNA damage that is indicative of UV radiation (C>T mutations, which are called “UV signature mutations”).

We recognize that this proposed order has regulatory limitations that prevent the FDA from instituting restrictions for certain populations. Therefore, we encourage the agency to move forward with supplemental regulations that will completely restrict minors under the age of 18 from using tanning devices. Since 2.3 million teens tan indoors in the United States annually, restricting teens’ access to indoor tanning is critical to preventing skin cancer. In a survey of high school students in grades 9 through 12, 49% of those who had reported using an indoor tanning device had done so 10 or more times within the past year.⁸ The tanning industry has specifically targeted young and vulnerable populations and provided false and misleading health information about indoor tanning.^{9,10} Recognizing the dangers of tanning beds for minors, California, New Jersey, New York, Vermont, and Texas have passed laws prohibiting the use of indoor tanning devices by individuals under 18 years of age.

We are encouraged to see that the FDA is proposing to require a label be affixed on the device highlighting, among other warnings and contraindications, against the use of indoor tanning for those under the age of 18. We are concerned, however, that the proposed height requirement of 10 millimeters is insufficient to communicate this contraindication and urge the agency to revise this proposed requirement to increase the height requirement for the warning statement. Unfortunately, knowledge about the dangers of indoor tanning often does not

³ Indoor tanning: the risks of ultraviolet radiation. *The U.S. Food and Drug Administration*. Retrieved August 1, 2013, from <http://www.fda.gov/ForConsumers>.

⁴ The International Agency for Research on Cancer Working Group on artificial ultraviolet (UV) light and skin cancer. The association of use of sunbeds with cutaneous malignant melanoma and other skin cancers: A systematic review. *International Journal of Cancer*, 2007 Mar 1;120(5):1116-22.

⁵ Ferrucci LM et al. Indoor tanning and risk of early onset basal cell carcinoma. *Journal of the American Academy of Dermatology*, 2012 Oct; 67(4):552-62.

⁶ Lazovich et al. Indoor Tanning and risk of melanoma: a case-control study in a highly exposed population. *Cancer Epidemiology, Biomarkers & Prevention*, 2010 Oct; 19(6):1557-68.

⁷ Zhang M et al. Use of tanning beds and incidence of cancer. *Journal of Clinical Oncology*, 2012 May; 30, 1588-1593.

⁸ Guy GP et al. Use of indoor tanning devices by high school students in the United States, 2009. *Preventing Chronic Disease*, 2011;8(5):A116.


⁹ Freeman S et al. UV tanning advertisements in high school newspapers. *Archives of Dermatology*, 2006 Apr; 142(4):460-2.

¹⁰ U.S. House of Representatives Committee on Energy and Commerce Minority Staff. False and Misleading Health Information Provided to Teens by the Indoor Tanning Industry: An Investigative Report. 2012.

change behavior,¹¹ and young people in particular believe that a tanned appearance is attractive and healthy.¹² Thus, restrictions for minors, rather than warnings, would be more effective to reduce the impact of skin cancer developed as a result of indoor tanning.

The MRA thanks the FDA for their leadership in protecting the public from dangerous tanning devices, and we encourage the agency to issue further regulations that will completely restrict access for minors under the age of 18 years. The evidence is clear – tanning beds are not safe, and we need to keep young people out of them. Increased efforts are needed to prevent many from receiving a diagnosis of skin cancer in the future. Thank you again for the opportunity to submit our comments. We commend the FDA for proposing this reclassification and for beginning the important process of protecting the public's health.

Sincerely,

A handwritten signature in cursive script that reads "Wendy Selig".

Wendy K.D. Selig
MRA President and Chief Executive Officer

¹¹ Monfrecola G et al. What do young people think about the dangers of sunbathing, skin cancer and sunbeds? A questionnaire survey among Italians. *Photodermatol Photoimmunol Photomed*, 2000; 16(1):15-18.

¹² Cokkinides V et al. Trends in sunburns, sun protection practices, and attitudes toward sun exposure protection and tanning among US adolescents, 1998-2004. *Pediatrics*, 2006 Sept; 118(3):853-864.