

October 4, 2022

Robert M. Califf, M.D., Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Finalization of Sunlamp Rule and Amendment to Performance Standard

Dear Commissioner Califf:

The National Council on Skin Cancer Prevention (NCSCP)—representing more than 40 organizations, agencies, and associations devoted to educating the public about skin cancer and the risks of ultraviolet (UV) light exposure—respectfully requests that the Food and Drug Administration, working with the Department of Health and Human Services, finalize the proposed rules entitled *General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products* (Docket No. FDA-2015-N-1765); and the *Sunlamp Products; Proposed Amendment to Performance Standard* (Docket No. FDA-1998-N-0880) published by the FDA in the Federal Register on December 22, 2015 (80 Fed. Reg. 79493 and 80 Fed. Reg. 79505 et seq.) Sunlamp regulation is a high priority for the NCSCP.

NCSCP members represent the nation’s premier researchers, clinicians, and advocates for melanoma and nonmelanoma skin cancer prevention. As such, we remain very concerned that the public’s health continues to be at risk from the current state of insufficient sunlamp regulation. Therefore, we encourage the FDA’s expeditious finalization of rules restricting minors’ use of sunlamps, requiring risk acknowledgement certification from adults and strengthening the sunlamp performance standards.

The NCSCP strongly opposes indoor tanning for anyone, and especially for minors. Additionally, educating the public about the health risks of indoor tanning is extremely important to help tackle the serious epidemic of skin cancer in the U.S. Prohibiting the use of tanning beds by individuals younger than 18 will result in reduced incidence of skin cancer particularly among young women. This is completely consistent with the goal of the President’s Cancer Moonshot and its target of reducing the death rate from cancer by at least 50 percent over the next 25 years through better treatment outcomes and prevention efforts.¹

We again commend the FDA for issuing the proposed rule prohibiting minors under age 18 throughout the U.S. from using tanning beds and requiring that adult tanning bed users be informed about the serious health risks of indoor tanning through a risk acknowledgement certification – including the increased risk of developing potentially fatal melanoma and other skin cancers. As stated in many past comment letters from our members, parental consent is inadequate to protect children and adolescents from the risks of indoor tanning, particularly exposure to UV radiation – a known human carcinogen.

Skin Cancer is the Most Commonly Diagnosed Cancer in the USⁱⁱ

Skin cancer is the most commonly occurring cancer and current estimates are that one in five Americans will develop skin cancer in their lifetime.ⁱⁱⁱ Melanoma is the most common form of cancer for young adults ages 25-29 and the second most common form of cancer for adolescents and young adults 15-25 years old.^{iv} Exposure to UV radiation from tanning beds at young ages contributes to the development of skin cancer, including the potentially deadly melanoma, in young people.^v The cost of treating all skin cancers in the U.S. is estimated at \$8.1 billion each year.^{vi} Clearly, swift action must be taken to reduce the risks associated with skin cancer.

Sunlamp Products Increase Users' Risk of Developing Skin Cancer

Sunlamp products, otherwise known as indoor tanning beds and booths, emit UV radiation that is a known human carcinogen.^{vii} Studies have found that indoor tanning devices can emit UV radiation in amounts 10 to 15 times higher than the sun at its peak intensity.^{viii} Evidence from several studies has shown that exposure to UV radiation from indoor tanning devices is associated with an increased risk of melanoma and nonmelanoma skin cancer (NMSC), including squamous cell carcinoma and basal cell carcinoma.^{ix} Each year, more than 419,000 cases of skin cancer, including both melanoma and NMSC, are linked to indoor tanning in the U.S. alone.^x Other studies have found a 59 percent increase in the risk of melanoma in those who have been exposed to UV radiation from indoor tanning, and the risk increases with each use.^{xi} Even a single indoor tanning session can increase users' risk of developing squamous cell carcinoma by 67 percent and basal cell carcinoma by 29 percent.^{xii} Despite these significant risks, approximately 7.8 million adults in the United States still engage in indoor tanning.^{xiii}

Currently, 22 states plus the District of Columbia prohibit people younger than 18 from using indoor tanning devices.^{xiv} Globally, 13 countries have banned indoor tanning for people younger than age 18 and two countries have banned indoor tanning altogether.^{xv}

The FDA is in a unique position to finish what was started several years ago with the indoor tanning ban for minors and the proposed rule that was published, but not finalized. Finalizing the proposed sunlamp rules will have a significant impact in reducing the incidence of melanoma and other skin cancers in the United States and be an important step towards achieving President Biden's Cancer Moonshot goals. The NCSCP urges FDA to stay true to the stated timeline and finalize the rules in 2022.

We request to meet with FDA and look forward to continuing our collaboration in furtherance of protecting the public's health. Should you have any questions, please contact John Antonishak, at 301.801.4422 or antonishak@skincancerprevention.org.

The endorsing National Council organizations listed below thank you for considering our views.

Sincerely,



John D. Antonishak
NCSCP Executive Director



Boris D. Lushniak, MD, MPH
NCSCP Co-Chair
University of Maryland
Former Acting U.S. Surgeon General



Becky Kamowitz
NCSCP Co-Chair
The Skin Cancer Foundation

Endorsing Organizations:

AIM at Melanoma
American Academy of Dermatology Association
American Academy of Pediatrics
American Melanoma Foundation
American Society for Dermatologic Surgery Association
American Society for Mohs Surgery
Arizona Skin Cancer Foundation
Colette Coyne Melanoma Awareness Campaign
Dermatology Nurses' Association
F Cancer
IMPACT Melanoma
Jack H. Marson II Melanoma Foundation
Jason Farley All In For A Cure Foundation
Melanoma Research Alliance
Melanoma Research Foundation
Outrun the Sun
Prevent Cancer Foundation
The Skin Cancer Foundation
Sun Safety for Kids
Society of Behavioral Medicine
Warriors Against Melanoma

ⁱ The White House, "Fact Sheet: President Biden Reignites Cancer Moonshot to End Cancer as We Know it," February 02, 2022, Statements and Releases

ⁱⁱ Cancer Facts and Figures 2022. American Cancer Society. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2022/2022-cancer-facts-and-figures.pdf>. Accessed September 1, 2022

ⁱⁱⁱ Stern RS. Prevalence of a history of skin cancer in 2007: results of an incidence-based model. *Arch Dermatol.* 2010 Mar;146(3):279-82; and Robinson JK. Sun Exposure, Sun Protection, and Vitamin D. *JAMA* 2005; 294:1541-43.

^{iv} Surveillance, Epidemiology, and End Results (SEER) program 18 registries. Data run July 25, 2018.

^v Schulman JM, Fisher DE. Indoor ultraviolet tanning and skin cancer: health risks and opportunities. *Curr Opin Oncol.* 2009;21(2):144-149. doi:10.1097/CCO.0b013e3283252fc5

^{vi} Guy GP Jr, Machlin SR, Ekwueme DU, Yabroff KR. Prevalence and costs of skin cancer treatment in the U.S., 2002-2006 and 2007-2011. *Am J Prev Med.* 2015 Feb;48(2):183-7.

^{vii} Ultraviolet-radiation-related exposures. Broad-spectrum UVR, pp. 1-5. NTP (National Toxicology Program). 2014. *Report on Carcinogens*, Thirteenth Edition. Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service. <http://ntp.niehs.nih.gov/ntp/roc/content/profiles/ultravioletradiationrelatedexposures.pdf>. Accessed January 26, 2018.

^{viii} Le Clair MZ, Cockburn MG. Tanning bed use and melanoma: Establishing risk and improving prevention interventions. *Prev Med Rep.* 2016; 3:139-144. Published 2016 Jan 14. doi:10.1016/j.pmedr.2015.11.016

^{ix} See, eg, Whitmore SE, Morison WL, Potten CS, Chadwick C. Tanning salon exposure and molecular alterations. *J Am Acad Dermatol* 2001;44:775-80. See also Swerdlow AJ, Weinstock MA. Do tanning lamps cause melanoma? An epidemiologic assessment. *J Am Acad Dermatol* 1998;38:89-98; 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 March 1;120:111-122; Karagas M, et al. "Use of tanning devices and risk of basal cell and squamous cell skin cancers." *Journal of the National Cancer Institute.* 2002 February 6;94(3):224-6.

^x Wehner MR, Chren M, Nameth D, et al. International Prevalence of Indoor Tanning: A Systematic Review and Meta-analysis. *JAMA Dermatol.* 2014;(). doi:10.1001/jamadermatol.2013.6896.

^{xi} Lazovich, D, et al. "Indoor Tanning and Risk of Melanoma: A Case-Control Study in a Highly Exposed Population." *Cancer Epidemiol Biomarkers Prev.* 2010 June;19(6):1557-1568; 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 March 1;120:111-1122; Cutaneous melanoma attributable to sunbed use: systematic review and meta-analysis. *British Medical Journal* 2012;345:e4757; Corrections: Cutaneous melanoma attributable to sunbed use: systematic review and meta-analysis. *British Medical Journal* 2012;345:e8503.

^{xii} Wehner MR, Shive ML, Chren MM, Han J, Qureshi AA, Linos E. Indoor tanning and non-melanoma skin cancer: systematic review and meta-analysis. *BMJ*. 2012 Oct 2;345:e5909.

^{xiii} Guy GP Jr, Watson M, Seidenberg AB, Hartman AM, Holman DM, Perna F. Trends in indoor tanning and its association with sunburn among U.S. adults. *J Am Acad Dermatol*. 2017;76(6):1191-1193. doi:10.1016/j.jaad.2017.01.022

^{xiv} Indoor tanning restrictions for minors — a state-by-state comparison. NCSL, National Conference of State Legislatures. <http://www.ncsl.org/research/health/indoor-tanning-restrictions.aspx>. Accessed March 25, 2022.

^{xv} Skin cancer: indoor tanning is not safe. Centers for Disease Control and Prevention, http://www.cdc.gov/cancer/skin/basic_info/indoor_tanning.htm. Last updated January 5, 2016, last reviewed January 22, 2016. Accessed January 31, 2018.