

March 11, 2021

Janet Woodcock, M.D. Acting 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 Acting Commissioner Woodcock:

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 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. We support a restriction on the production and sale of indoor tanning equipment. 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.

We 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 ultraviolet (UV) radiation – a known human carcinogen.

More Than Two People Die of Skin Cancer in the U.S. Every Hourⁱ

Skin cancer is the most commonly occurring cancer and current estimates are that one in five Americans will develop skin cancer in his or her lifetime.ⁱⁱ 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.ⁱⁱⁱ 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.^{iv} The cost of treating all skin cancers in the U.S. is estimated at \$8.1 billion each year.^v 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 ultraviolet (UV) radiation that is a known human carcinogen.^{vi} 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.^{vii} 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.^{viii} 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.^{ix} 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.^x 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.^{xi} Despite these significant risks, nearly 30 million people in the United States use indoor tanning devices each year.^{xii}

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

Federal Regulatory Agencies Must Act Now to Reduce the Risks Posed by Sunlamp Products

Given the pressing need to fight skin cancer, and the fact that the use of sunlamp products is an entirely avoidable risk factor, we support the FDA's actions to change the regulation of sunlamp products in a way that recognizes their clear hazard to public health. We fully supported the FDA's prior efforts to reclassify sunlamps as Class II devices and applaud the Agency for continuing to work to reduce skin cancer risks by submitting a proposed rule to OMB to further regulate sunlamp products. We urge the Biden Administration, including FDA, the Department of Health and Human Services, and the Office of Management and Budget, to publish this critical proposed rule as a final rule, as it provides an important step in the fight to eradicate skin cancer. It is especially important to protect our youth from this preventable cancer risk.

FDA is in a unique position to finish what it started several years ago with the indoor tanning ban for minors and the proposed rule that was published, but not finalized.

Finalizing the two proposed sunlamp rules will have a significant impact in reducing the incidence of melanoma and other skin cancers in the United States, so we urge you to act quickly to formalize these rules.

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

Also, we respectfully request a meeting with FDA to discuss this important issue.

We look forward to continuing to collaborate with the FDA in furtherance of protecting the public's health. Should you have any questions, please contact me, at 301.801.4422 or antonishak@skincancerprevention.org.

Sincerely,



John D. Antonishak
NCSCP Executive Director

Endorsing Organizations:

AIM at Melanoma
American Academy of Dermatology Association
American Academy of Pediatrics
American Cancer Society, Cancer Action Network
American College of Mohs Surgery
American Melanoma Foundation
American Skin Association
American Society for Mohs Surgery
Children's Melanoma Prevention Foundation
Colette Coyne Melanoma Awareness Campaign
Dermatology Nurses' Association
Fuck Cancer
IMPACT Melanoma
Jack H. Marston II Melanoma Research Fund
Jason Farley All in for the Cure Foundation
Melanoma Research Alliance
Melanoma Research Foundation
Outrun the Sun
Polka Dot Mama Melanoma Foundation
Prevent Cancer Foundation
Society of Behavioral Medicine
Society for Pediatric Dermatology
Sun Safety for Kids
The Skin Cancer Foundation
Warriors Against Melanoma

ⁱ Cancer Facts and Figures 2021. American Cancer Society. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf>. Accessed January 13, 2021

ⁱⁱ Stern RS. Rprevalence 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.

ⁱⁱⁱ Surveillance, Epidemiology, and End Results (SEER) program 18 registries. Data run July 25, 2018.

^{iv} 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

^v 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.

^{vi} 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.

^{vii} 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

^{viii} 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;120:111-1122; 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.

^{ix} 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..

^x 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.

^{xi} 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.

^{xii} Kwon HT, Mayer JA, Walker KK, Yu H, Lewis EC, Belch GE. Promotion of frequent tanning sessions by indoor tanning facilities: two studies. *J Am Acad Dermatol* 2002;46:700-5.

^{xiii} 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 January 29, 2018

^{xiv} 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.