

Congress of the United States

Washington, DC 20510

September 30, 2022

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

Dear Commissioner Califf,

We greatly appreciate the Food and Drug Administration's (FDA) response to our letter of August 6, 2021, which expressly encouraged the FDA to finalize its 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).¹ In its response the FDA expressly stated that "the proposed rulemaking continues to be a priority for both the Agency and the administration, and it is currently listed as part of the administration's Unified Agenda with a target date for a final rule in May 2022."

We are deeply concerned that the public's health continues to be at risk due to insufficient sunlamp regulation and believe the public would greatly benefit from FDA's finalizing these proposed rules. We strongly encourage the FDA to expeditiously finalize rules to restrict minors' use of sunlamps, to require risk acknowledgement certification from adults, and to strengthen the sunlamp performance standards.

Banning 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, with the ultimate objective of ending cancer as we know it today.² According to the American Academy of Dermatology Association, indoor tanning increases the risk of developing the two most common types of skin cancer—squamous cell carcinoma and basal cell carcinoma—by 58 percent and 24 percent, respectively.³ Using tanning beds before age 20 can increase one's chances of developing melanoma by 47 percent and the risk increases with each use.⁴ Furthermore, women younger than 30 are six times more likely to develop melanoma if they tan indoors.⁵

The FDA's proposed rule, once finalized, would take significant steps towards reducing the health risks from sunlamps by prohibiting minors under age 18 throughout the United State from using tanning beds and requiring adult tanning bed users be informed about the serious health risks of indoor

¹ Docket No. FDA-2015-N-1765; Docket No. FDA-1998-N-0880

² The White House, "Fact Sheet: President Biden Reignites Cancer Moonshot to End Cancer as We Know it," February 02, 2022, Statements and Releases

³ An S, Kim K, Moon S, et al. Indoor Tanning and the Risk of Overall and Early-Onset Melanoma and Non-Melanoma Skin Cancer: Systematic Review and Meta-Analysis. *Cancers* (Basel). 2021;13(23):5940. Published 2021 Nov 25. doi: 10.3390/cancers13235940

⁴ Ibid

⁵ Lazovich D, Isaksson Vogel R, Weinstock MA, Nelson HH, Ahmed RL, Berwick M. Association Between Indoor Tanning and Melanoma in Younger Men and Women, *JAMA Dermatol*. 2016; 152(3): 268-275. Doi.10.1001/jamadermatol.2015.2938

tanning – including the increased risk of developing potentially fatal melanoma and other skin cancers – through a risk acknowledgement certification. The proposed rules would also ensure that performance standards for sunlamp products are updated to reflect current science and research. Updating these regulations would help educate potential users by making sunlamp product warning labels more visible and by directing manufacturers to include the warning labels in informational brochures and materials used for marketing sunlamp products.

We are confident that enacting these proposed rules would reduce the prevalence of skin cancer in the United States, as a growing body of evidence shows that 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. Data from several studies have 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. Each year, more than 419,000 cases of skin cancer, including both melanoma and NMSC, are linked to indoor tanning in the United States alone.⁶ 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.⁷ 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.⁸ Despite these significant risks, nearly 30 million people in the United States use indoor tanning devices each year.⁹

Currently, twenty-two states and the District of Columbia prohibit people younger than 18 from using indoor tanning devices. Globally, thirteen countries have banned indoor tanning for individuals younger than age 18, and two countries have banned indoor tanning altogether. We believe that it is time for the United States to follow suit and prohibit minors from using indoor tanning devices at the federal level.

We strongly urge the Biden Administration – including FDA, the Department of Health and Human Services, and the Office of Management and Budget – to publish these critical proposed rules as final rules, as we believe doing so is a critical and requisite step in the fight to eradicate skin cancer. It is especially important to protect our youth from this preventable cancer risk.

We look forward to continuing working with FDA in furtherance of protecting the public's health.

Sincerely,

⁶ Wehner MR, Chren M, Nameth D, et al. International Prevalence of Indoor Tanning: A Systematic Review and Meta-analysis. *JAMA Dermatol.* 2014;150(4):390–400. doi:10.1001/jamadermatol.2013.6896

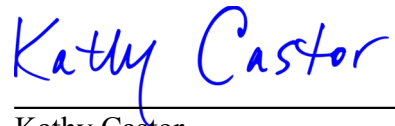
⁷ An S, Kim K, Moon S, et al. Indoor Tanning and the Risk of Overall and Early-Onset Melanoma and Non-Melanoma Skin Cancer: Systematic Review and Meta-Analysis. *Cancers (Basel).* 2021;13(23):5940. Published 2021 Nov 25. doi: 10.3390/cancers13235940

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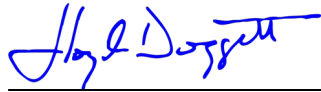
⁹ Choi K, Lazovich D, Southwell B, Forster J, Rolnick SJ, Jackson J. Prevalence and characteristics of indoor tanning use among men and women in the United States. *Arch Dermatol.* 2010 Dec;146(12):1356-61. doi: 10.1001/archdermatol.2010.355. PMID: 21173319; PMCID: PMC8966465.



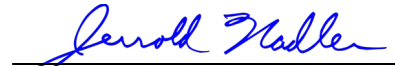
Carolyn B. Maloney
Member of Congress



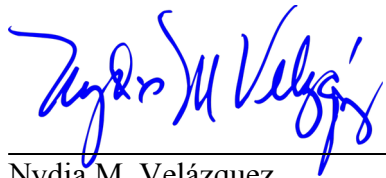
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