



American Association
for Cancer Research

FINDING CURES TOGETHER™



Association of
American Cancer Institutes

VIA ELECTRONIC SUBMISSION

March 21, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2015-N-1765, General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products; Proposed Rule

To Whom It May Concern:

The American Association for Cancer Research (AACR), with more than 34,000 members, is the world's first and largest professional organization dedicated to preventing and curing cancer through research, education, communication, and collaboration. The Association of American Cancer Institutes (AACI) comprises 95 leading cancer research centers in the United States, including National Cancer Institute (NCI)-designated centers and academic-based cancer research programs that receive NCI support. On behalf of the AACR and AACI, we are pleased to offer the following comments in strong support of the Food and Drug Administration's (FDA) proposed rule to prevent persons under the age of 18 from using indoor tanning facilities, and to require indoor tanning facility customers over the age of 18 to sign paperwork acknowledging the risks of indoor tanning. This rule should be finalized and implemented as quickly as possible, and we also encourage the FDA to consider strong enforcement mechanisms for the rule.

There is a growing body of scientific evidence that shows indoor tanning dramatically increases a person's skin cancer risk, including the risk of melanoma, the most deadly form of skin cancer. Melanoma is a devastating disease that more than 76,000 Americans are expected to be diagnosed with in 2016, and which will claim the lives of 10,000 Americans this year. The American Academy of Dermatology found that those individuals who have been exposed to ultraviolet (UV) radiation from indoor tanning are 59 percent more likely to develop melanoma than those who have never tanned indoors.

These skin cancer risks are further increased by indoor tanning before the age of 18. By prohibiting the use of tanning beds by those under age 18, this proposed rule would reduce the

risk of skin cancer in a vulnerable population. Young people are not only at risk for solar radiation exposures that can increase their risk of skin cancer, but also they are typically the demographic most likely to use tanning beds. Melanoma rates among young women have soared 50 percent since the 1980s, a trend that has paralleled an increase in the use of indoor tanning facilities, according to the NCI. A study published in 2014 in the AACR journal, *Cancer Epidemiology, Biomarkers & Prevention*, also supports this finding.¹ The study found that the development of melanoma was more closely related to sun exposure early in life than in adulthood, especially in Caucasian women. The women who had at least five blistering sunburns between the ages of 15 and 20 had an 80 percent increased risk for melanoma and a 68 percent increased risk for basal cell carcinoma and squamous cell carcinoma. Twenty-four percent of the women who had the higher risk had used tanning beds. The increased risk found through this study is especially troubling when coupled with the fact that by age 17, more than 35 percent of Caucasian females have used tanning beds, many of them tanning more than 10 times per year.²

In January 2015, the AACR and AACI joined the American Cancer Society Cancer Action Network and 17 other national scientific, medical professional and patient advocacy organizations in a joint statement that called for the following: (1) state and federal legislation to prohibit the use of indoor tanning by individuals under age 18; (2) educational efforts that effectively communicate the risks of indoor tanning to teens and their parents; and, (3) counter-advertising to de-normalize the perceived “beauty” of tanned skin. We are pleased that the proposed rule addresses two of the three action items called for in the statement.

In addition to being consistent with the joint statement noted above, this proposed rule aligns with other federal and international recommendations. The Centers for Disease Control and Prevention has issued a recommendation for individuals to avoid indoor tanning with ultraviolet (UV) sunlamps, sunbeds and tanning booths to reduce the risk of skin cancer, including melanoma.³ Furthermore, the World Health Organization (WHO) International Agency for Research on Cancer has classified UV radiation from tanning devices as carcinogenic to humans, in the same category as asbestos, tobacco, and plutonium.

The AACR and AACI also support the proposed requirement that adults receive and acknowledge the risks of indoor tanning upon their first usage of a tanning facility, and every six months thereafter. This is important, since surveys have shown that many people do not understand the health risks associated with indoor tanning. For example, a 2012 study commissioned by the House Energy & Commerce Committee found that even employees of tanning facilities are unaware of the potential adverse health effects associated with UV sunlamps and sunbeds.

The AACR and AACI appreciate the opportunity to comment on this proposed rule, and we urge the FDA to move quickly to finalize it. By prohibiting the use of indoor tanning facilities by those under age 18 and requiring indoor tanning facility customers over the age of 18 to sign

¹ Shaowei Wu, Jiali Han, Francine Laden and Abrar Quereshi. Long-term ultraviolet flux, other potential risk factors, and skin cancer risk: a cohort study. *Cancer Epidemiol Biomarkers Prev* 2014; 23(6): 1-10.

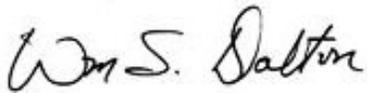
² American Cancer Society Cancer Action Network. et al. Joint Policy Statement on Indoor Tanning. January, 2015.

³ Centers for Disease Control and Prevention.
http://www.cdc.gov/cancer/skin/basic_info/indoor_tanning.htm

paperwork acknowledging the risks of indoor tanning, it is our hope that minors and adults will be further protected from this dangerous practice and ultimately, the rates of skin cancer can be reduced.

If we can provide any additional information or assistance, please do not hesitate to contact Mary Lee Watts, AACR Director of Government Relations & Advocacy, at (202) 898-6499 or marylee.watts@aacr.org or Jennifer Pegher, AACI Director of Government Relations, at (412) 647-0557 or jen@aacr-cancer.org.

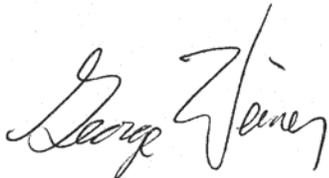
Sincerely,



William S. Dalton, PhD, MD Chair, AACR
Science Policy & Government Affairs
Committee



Margaret Foti, PhD, MD (hc)
AACR Chief Executive Officer



George J. Weiner, MD
AACI President



Barbara Duffy Stewart, MPH
AACI Executive Director