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March 14, 2016

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

*RE: [Docket No. FDA-2015-N-1765] General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products*

Dear Dr. Califf,

On behalf of the dermatologists in North Carolina, we are writing in strong support of the Food and Drug Administration's (FDA) proposed rule titled "General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products." The North Carolina Dermatology Association (NCDA) commends the FDA on its leadership in regulating sunlamps and for taking this important step to protect the public health. Together with the FDA's final rule reclassifying sunlamp products and the proposed rule updating sunlamp performance standards, this proposed rule will make a significant impact in reducing the incidence of skin cancer in the United States. We urge the FDA to finalize this proposed rule.

The NCDA has been a proponent of stronger regulation of the tanning industry and indoor tanning devices for many years. Just this past year, we championed an advocacy initiative here in North Carolina resulting in the passage of legislation banning teens from being able to access commercial indoor tanning beds. This was a huge public health victory for our state that will save lives and health care dollars. Other states have adopted similar measures, so the FDA should likewise take appropriate action on the proposed rule.

### **Sunlamp Restriction for Minors and Risk Certification for Adults are Critical in the Fight Against Skin Cancer**

Dermatologists on the front line in the battle against skin cancer are concerned about the rising incidence of melanoma and nonmelanoma skin cancers.<sup>1 2 3 4</sup> Of particular concern is the incidence of skin cancer in young people - melanoma is now the most common form of cancer

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<sup>1</sup> American Cancer Society. Cancer Facts & Figures 2016. Atlanta: American Cancer Society; 2016.

<sup>2</sup> Rogers HW, Weinstock MA, Feldman SR, Coldiron BM. Incidence Estimate of Nonmelanoma Skin Cancer (Keratinocyte Carcinomas) in the US Population, 2012. JAMA Dermatol. 2015 Apr 30. doi: 10.1001/jamadermatol.2015.1187.

<sup>3</sup> Christenson LJ, Borrowman TA, Vachon CM, Tollefson MM, Otley CC, Weaver AL, et al. Incidence of basal cell and squamous cell carcinomas in a population younger than 40 years. JAMA. 2005;294(6):681-690.

<sup>4</sup> Little EG, Eide MJ. Update on the current state of melanoma incidence. Derm Clin 2012;30(3), 355-361.

among young adults ages 25 to 29 and the second most common form of cancer for adolescents and young adults 15 to 29 years old.<sup>5</sup>

As evidenced by our tireless effort to get legislation passed here in North Carolina in 2015, the NCDA and North Carolina dermatologists are very concerned about the role that indoor tanning plays in these rising rates of skin cancer. Indoor tanning may cause upwards of 400,000 cases of skin cancer in the U.S. each year and emit ultraviolet (UV) radiation that is a known human carcinogen.<sup>11 12 13</sup> 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.<sup>7</sup> Moreover, indoor tanning before age 24 increases one's risk of developing basal cell carcinoma by age 50.<sup>14</sup>

The NCDA strongly opposes indoor tanning and supports a restriction on the production and sale of indoor tanning equipment for nonmedical purposes. Educating the public about the risks associated with indoor tanning is therefore extremely important if the U.S. wants to seriously tackle the epidemic of skin cancer. We commend the FDA for issuing this proposed rule that would restrict the use of indoor tanning equipment for minors and require that adult tanning bed users are informed about the serious health risks of indoor tanning. This proposal is a critical step in reversing the growing incidence of skin cancer and we urge the FDA to finalize the proposed rule.

### **Parental Consent Inadequate to Protect Children and Adolescents**

The NCDA believes that the FDA has a responsibility to protect the public, and children in particular, from the harms of UV radiation. Much like the FDA regulates the use, distribution, and sale of tobacco, the FDA should also regulate sunlamps. Both tobacco and UV from sunlamps are known carcinogens, and their regulation is consistent with the FDA's public health mission. Unfortunately, parental consent laws have proven to be inadequate in protecting minors from the dangers of indoor tanning given the inconsistent enforcement of parental consent laws across the states, as noted by in the Surgeon General's Call to Action to Prevent Skin Cancer.<sup>15</sup> Without reliable and active enforcement, state consent laws become virtually meaningless. For these reasons, we believe that an age restriction is appropriate and the only genuine way to ensure that minors do not continue to engage in this risky behavior.

### **Risk Certification Necessary to Ensure Adults Understand Skin Cancer Risks**

The NCDA further supports the FDA's proposed certification form that adults would have to sign before using tanning beds and booths. This form is necessary to ensure that adults are fully apprised of the risks associated with indoor tanning. Unfortunately, there have been misinformation campaigns by some indoor tanning salons seeking to portray sunlamp use as safe and beneficial. We believe that additional efforts are necessary to continue to correct this misinformation and educate adults about the risks associated with indoor tanning.

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<sup>5</sup> Melanoma of the Skin, Cancer Fact Sheets, National Cancer Institute, SEER database, 2007. <http://seer.cancer.gov>.

<sup>11</sup> Wehner M, Chren M-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.

<sup>12</sup>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.

<sup>13</sup> 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/pubhealth/roc/roc13/>.

<sup>14</sup> Karagas MR, et al. Early-onset basal cell carcinoma and indoor tanning: a population-based study. *Pediatrics*. 2014 Jul;134(1):e4-12. doi: 10.1542/peds.2013-3559.

<sup>15</sup> U.S. Department of Health and Human Services, Office of the Surgeon General, The Surgeon General's Call to Action to Prevent Skin Cancer, 34 (2014).

## Conclusion

The North Carolina Dermatology Association and our state's dermatologists appreciate the opportunity to share our support for the FDA's proposed rule restricting minors' use of sunlamps and requiring that adults acknowledge the risks associated with sunlamps. We urge the FDA to finalize the rule to protect the public's health from the dangers of UV radiation.

Sincerely,

Handwritten signature of Pamela J. Guest in cursive script.

Pamela J. Guest, MD  
President  
North Carolina Dermatology Association

Handwritten signature of W. Alan Skipper in cursive script.

W. Alan Skipper, CAE  
Executive Director  
North Carolina Dermatology Association