Congress of the United States Washington, DC 20515

August 6, 2021

Acting Commissioner Janet Woodcock Food and Drug Administration 10903 New Hampshire Ave Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock:

We write to respectfully request that the U.S. Food and Drug Administration (FDA), in coordination with the Department of Health and Human Services, work to reduce the prevalence of melanoma and skin cancer in the United States by finalizing rules to protect the American public from the dangers of sunlamps.

As you are aware, skin cancer is the most commonly occurring cancer in the United States, and current estimates project that one in five Americans will develop skin cancer in their lifetime. [11] Alarmingly, more than two people die of skin cancer in the United States every hour. [22] Melanoma is the most common form of cancer for young adults ages 25-29 and the second most common form of cancer for young adults 15-25 years old. [33] Exposure to UV radiation from tanning beds at young ages contributes to the tragically high rates of young people developing skin cancer, including potentially deadly melanoma. The cost of treating skin cancer in the United States is estimated at \$8.1 billion each year. [44] Clearly, swift action must be taken to reduce the risks associated with skin cancer.

We commend the FDA for issuing the proposed rules entitled *General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products* (Docket No. FDA-2015-N-1765); and *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, respectively). 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 should these proposed rules be finalized. Therefore, we 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.

These proposed rules 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 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. 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. 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. Despite these significant risks, nearly 30 million people in the United States use indoor tanning devices each year.

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 applaud FDA's reclassification of sunlamps as Class II devices and its continuing work to minimize the risk of skin cancer. To that purpose, we 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,

Carolyn B. Maloney Member of Congress

Carolyn B. Malore

Ted W. Lieu Member of Congress

Ted W. Lien

André Carson Member of Congress Nydia M. Velázquez Member of Congress

Rosa L. DeLauro Member of Congress

Kathy Castor Member of Congress

Kathy Castor

¹ Stern, RS. Prevalence of a history of skin cancer in 2007: results of an incidence-based model. Arch Dermatol 2010; 146(3):279-282.

² Rogers HW, Weinstock MA, Feldman SR, Coldiron BM. Incidence estimate of nonmelanoma skin cancer (keratinocyte carcinomas) in the US population, 2012. JAMA Dermatol 2015; 151(10):1081-1086.

³ Skin Cancer Foundation: Skin cancer facts: Melanoma. Available at skincancer.org/skin-cancer-information/skin-cancer-facts#melanoma. Accessed March 23, 2021.

⁴ Guy, G., Machlin, S., Ekwueme, D., & D., & Samp; Yabroff, K. (2015, February). Prevalence and costs of skin cancer treatment in the U.S., 2002-2006 and 2007-2011. Retrieved March 23, 2021, from

 $https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4603424/\#:\sim:text=Between\%202002\%E2\%80\%932006\%20 and \%202007\%E2\%80\%932011\%2C\%20 the\%20 average\%20 annual, \%3D0.005\%2C\%20 Table\%202).$

⁵ Skin cancer facts & Damp; statistics. (2021, January 21). Retrieved March 23, 2021, from https://www.skincancer.org/skin-cancer-information/skin-cancer-facts/

⁶ Lazovich D, Vogel RI, Berwick M, Weinstock MA, Anderson KE, Warshaw EM. Indoor tanning and risk of melanoma: a case-control study in a highly exposed population. Cancer Epidemiol Biomarkers Prev. 2010 Jun;19(6):1557-68. doi: 10.1158/1055-9965.EPI-09-1249. Epub 2010 May 26. PMID: 20507845; PMCID: PMC2883000.

⁷ 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.