

Melanoma

Research Alliance

January 20, 2016

Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852
Submitted via www.regulations.gov

RE: Docket No. FDA-2015-N-1765

Dear Food and Drug Administration:

On behalf of the Melanoma Research Alliance (MRA), thank you for the opportunity to provide comments in response to the proposed rule “General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products” (Docket No. FDA-2015-N-1765) published in the *Federal Register* on December 22, 2015. **MRA supports the proposed rule and applauds the Food and Drug Administration (FDA) for taking this latest step to protect the public from the dangers of tanning devices.**

MRA is a public charity whose mission is to end suffering and death due to melanoma by collaborating with all stakeholders to accelerate powerful research, advance cures for all patients, and prevent more melanomas. Since 2007, MRA has awarded nearly \$68 million to 180 of the most innovative research projects in 14 countries that have the potential to transform the prevention, diagnosis, and treatment of melanoma.

Melanoma is the fifth most common cancer in the United States, second most common cancer in men and women ages 15 to 29, and its incidence has continued to rise over the past 30 years. This year more than 76,000 Americans will be diagnosed with new melanoma – one every eight minutes – and more than 9,700 will die of the disease. If caught in its earliest stages, melanoma is curable with surgery; however, patients diagnosed with Stage IV metastatic melanoma have a median survival of less than one year after diagnosis.

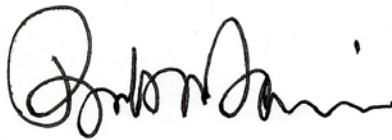
Sadly, many melanomas could be prevented by reducing exposure to ultraviolet (UV) radiation from the sun and tanning beds as it is the most modifiable risk factor. The evidence linking the use of UV tanning devices to melanoma and other skin cancers has been well-documented in the scientific literature and is reviewed in the FDA docket. UV-emitting sunlamp products are carcinogenic to humans and a known health danger as recognized by leading health authorities, including the World Health Organization, US Centers for Disease Control and Prevention, and US Department of Health and Human Services.

MRA urges FDA to consider a total ban on the sale and use of indoor tanning equipment for non-medical purposes by both minors and adults. But, until then, this proposed rule will protect the health of children, who are particularly vulnerable and face a higher risk of developing skin cancer in their lifetime than individuals who begin tanning later as adults. Parental permission laws do not offer adequate protection for children. The tanning industry has specifically targeted the teen market and provided misleading information about the risks of indoor tanning as found in a 2012 investigation by the US

House of Representatives Committee on Energy and Commerce. Thus, **MRA supports the FDA's proposed rule to restrict the sale, distribution and use of sunlamp products, including restricting the use of indoor tanning devices to individuals 18 and older and requiring prospective users to sign a risk acknowledgement certification before use and every six months thereafter.** MRA recommends that the risk of skin cancer, including melanoma, be explicitly included in the acknowledgement certification.

The use of indoor tanning devices is a known and significant health threat, especially to young people, as they are clearly associated with increased risk for all skin cancers including deadly melanoma. We urge the FDA to finalize the proposed rule to restrict the sale, distribution and use of sunlamp products. MRA thanks the FDA for their leadership in protecting the public from dangerous tanning devices.

Sincerely,

A handwritten signature in black ink, appearing to read "Robin Davisson". The signature is fluid and cursive, with a prominent initial "R" and a long, sweeping underline.

Robin Davisson
MRA President and CEO-Elect