



American Medical Women's Association



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

**Comments on Proposed Rule
Restricted Sale, Distribution, and Use of Sunlamp Products
[Docket No. FDA-2015-N-1765]**

As members of the Patient, Consumer, and Public Health Coalition, we strongly support the proposed rule that bans minors (individuals under the age of 18) from using commercial tanning beds (sunlamp products). However, we think the age limit should be 21, as it is for alcohol, and as it is for cigarettes in more than 100 U.S. cities.¹

In 2013, our coalition submitted comments to the FDA recommending that the agency up-classify sunlamp devices from Class I (low risk devices) to Class III (high risk devices).² Unfortunately, the agency only up-classified the device to Class II (moderate risk devices). Now, in its proposed rule, the FDA cites studies that the devices are directly correlated to skin cancer including the most deadly form, melanoma. Since there are virtually no medical benefits to using commercial tanning beds and the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) classified indoor tanning devices as carcinogenic to humans,³ **we recommend that FDA ban the devices entirely (not just for users under age 18)**. At the very least the FDA should ban the devices for users under 21 and reclassify sunlamp

products as Class III (high risk devices). High-risk devices are ones that can cause substantial harm or even death, and clearly, sunlamps satisfy those criteria.

In the meantime, however, we support the requirement that adult users of indoor tanning salons sign a risk acknowledgment certificate, and the proposed rule's requirement that user manuals be provided by salon staff to other staff and any customer who asks for one.

Below are our specific comments on the proposed rule.

Age Restrictions on Tanning Devices

Young people, especially women (who use the devices more often than young men), are extremely vulnerable to the health risks of tanning devices. Using indoor tanning beds before age 35 can increase the risk of melanoma—the deadliest form of skin cancer—by 59%.⁴ The risk increases with the number of sunbed sessions and is higher if the person begins using tanning devices at a younger age.³ Medical evidence points to a “direct correlation between sunlamp product use among youths and their developing melanoma skin cancer.”⁵ Melanoma is a leading cause of cancer death in women ages 15 to 29 years.⁵ In 2013, the American Cancer Society (ACS) estimated 76,690 new cases of melanoma in the United States and 9,480 deaths from the disease during the year.⁶ Each year, approximately 400,000 cases of skin cancer (including melanoma) in the U.S. are caused by indoor tanning, according to the American Academy of Dermatology.⁴

A recent study showed that restrictions on access to tanning beds will reduce the number of young people using them. Female high school students in states with indoor tanning laws were less likely to engage in indoor tanning compared to students in states without any laws, according to the Centers for Disease Control and Prevention.⁷

The FDA's proposed rule banning use by minors under 18 will reinforce regulatory actions already taken by more than 40 states. Minors are banned from using commercial tanning beds in 11 states (California, Delaware, Illinois, Louisiana, Minnesota, Nevada, New Hampshire, North Carolina, Oregon, Texas, and Vermont) and the District of Columbia.⁶ Just this month, Kansas House lawmakers overwhelmingly passed a bill to ban minors from indoor tanning salons and the legislation has been sent to the state Senate.⁸

The FDA's proposed rule will protect minors in all states, but only under the age of 18. The cancer damage associated with sun tanning devices is substantial and could be avoided by stricter regulations.³ The FDA's proposed rule dovetails with recommendations from the IARC, which stated: “Policymakers should consider enacting measures, such as prohibiting minors and discouraging young adults from using indoor tanning facilities, to protect the general population from possible additional risk for melanoma.”⁹

We strongly support the proposed rule that would ban minors from using the devices and agree with the FDA that “by restricting sunlamp product use to individuals 18 and older, we would be protecting a subpopulation that generally tends to discount risk information and favor risk taking.”⁵ Unfortunately, however, young adults over 18 also tend to ignore risk information.

There is no logical reason to have an age limit of 18 for sunlamps, when the age limit is 21 for alcohol and tobacco products in more than 100 U.S. cities.

Prospective Users Signing Risk Acknowledgement Certificates

The proposed rule does not go far enough in protecting those 18 and older when it requires the owners of tanning salons to have those users sign a risk acknowledgement statement, which is supposed to counteract any false or misleading information about the devices. However, without an effective enforcement or monitoring policy established, it is unlikely tanning salon owners will comply with this part of the proposed rule. Congress found in 2012 that tanning salons were providing “false and misleading Information” to customers. Congress also found that 90 percent of operators stated to customer inquiries “that indoor tanning presented no risks.”⁵

Providing Sunlamp Product User Manuals

Until sunlamps are either tested as PMA devices or banned entirely, we support requiring that the user manuals for the devices be provided to anyone who requests them. However, this protection is too weak. The manuals should be provided by salon staff within 5 minutes of a request and the FDA should not allow the salon operator to merely provide the address of the manufacturer/distributor or the address of the 510(k) holder). The reason is simple: those two options greatly delay the availability of the information that clients need to make an informed choice. In addition, it puts a burden on clients who request information that could save their lives, rather than putting the onus on the tanning salon to provide information needed for informed consent regarding the use of dangerous devices.

Getting information from the manufacturer or distributor will inevitably take days, weeks, or months to receive. Getting the information from a 510(k) holder is completely ludicrous even assuming that person’s name and address can be accurately provided. The National Center for Health Research conducted a study on publicly available information regarding 510(k) medical devices and the Center found that the addresses provided were frequently out of date. Moreover, although the companies were required by law to provide information upon request, only 20% of the 510(k) holders provided the requested information in unredacted form.¹⁰

Conclusion

We strongly support the FDA’s proposed rule to ban the use of commercial tanning devices by minors. This would reduce the risk of skin cancer for many Americans. However, since the FDA has not required that sunlamps be carefully studied through the PMA process, **we recommend that the FDA go even further to protect the public health by banning commercial sunlamp products entirely.**

American Medical Women’s Association
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¹ Sandrick, B (December 8, 2015). More than 100 U.S. Cities Raise Smoking Age to 21. Cleveland.com http://www.cleveland.com/metro/index.ssf/2015/12/cleveland_follows_growing_nati.html

² Patient, Consumer, and Public Health Coalition (August 7, 2013). Comments on Proposed Order on “Reclassification of Ultraviolet Lamps for Tanning, Henceforth To Be Known as Sunlamp Products. Docket No. FDA-2013-N-0461.

³ BMJ (2012). Boniol M, *et al.* Cutaneous melanoma attributable to sunbed use: systematic review and meta-analysis. <http://www.bmj.com/content/345/bmj.e4757>

⁴ American Academy of Dermatology web page. <https://www.aad.org/advocacy/skin-cancer-and-indoor-tanning/stop-skin-cancer>

⁵ Federal Register (Tuesday, December 22, 2015). Proposed rule: General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products.

⁶ National Conference of State Legislatures. Web page: Indoor Tanning Restrictions For Minors – A State-By-State Comparison. <http://www.ncsl.org/research/health/indoor-tanning-restrictions.aspx>

⁷ Centers for Disease Control and Prevention (2014). Press Release: Rates of indoor tanning among female high school students lowest in states with multiple restrictions on youth access. <http://www.cdc.gov/media/releases/2014/p0213-indoor-tanning.html>

⁸ Associated Press (March 10, 2016). Lawmakers vote to ban Kansas minors from indoor tanning. Reported in the *Kansas City Star*. <http://www.kansascity.com/news/state/kansas/article65208207.html>

⁹ World Health Organization(WHO), International Agency for Research on Cancer (2006). Exposure to Artificial UV Radiation and Skin Cancer.

¹⁰ Zuckerman, D, Brown, P, and Das A (2014) Lack of Publicly Available Scientific Evidence on the Safety and Effectiveness of Implanted Medical Devices. *JAMA Intern Med*.