ASA
American Suntanning Association

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Office of Science Quality
Centers for Disease Control and Prevention
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This is a submission of an information quality request for correction.

Detailed description of the specific information that needs to be corrected.

The information that needs to be corrected is the entire section of the CDC's website titled "Indoor Tanning Is Not
Safe" at http://www.cdc.gov/cancer/skin/basic_info/indoor_tanning.htm.

The specific reasons for believing the information does not comply with OMB, HHS or CDC guidelines and is in error.

There is no scientific evidence that indoor tanning in commercial tanning salons increases the risk of melanoma. Information on the CDC's website titled "Indoor Tanning is Not Safe" that implies that indoor tanning in commercial tanning salons increases the risk of melanoma is incorrect. Dissemination of incorrect information about human health does not comply with HHS or CDC guidelines.

The section of the CDC's website titled "Indoor Tanning is Not Safe" conflates home use of artificial tanning devices with commercial tanning salon use of artificial tanning devices and uses the omnibus phrase "Indoor Tanning" to describe both. This is not appropriate because the risks associated with home use of artificial tanning devices are far different, and far greater, than the risks associated with commercial tanning salon use of artificial tanning devices. For example, Chen et al. 1998 found an OR of 1.13 (95% CI, 0.82-1.56) for melanoma risk from ever-use of "indoor tanning" but close examination of Chen et al. 1998 shows that this is an OR for conflated data from home use and commercial use. The separated-out results in Chen et al. 1998 show an

OR of 1.40 (95% CI, 0.97-2.04) for melanoma risk from home use and an OR of 0.79 (95% CI, 0.49-1.26) for melanoma risk from commercial use. Similarly, Walter et al. 1990 and Walter et al. 1999 found an OR of 1.54 (95% CI, 1.16-2.04) for melanoma risk from ever-use of "indoor tanning", but separated-out results showed an OR of 1.90 (95% CI, 1.11-3.31) for melanoma risk from home use and an OR of 0.92 (95% CI, 0.55-1.54) for commercial use, and Clough-Gorr et al. 2008 found an OR of 1.22 (95% CI, 0.83-1.79) for melanoma risk from ever-use of "indoor tanning", but separated-out results showed an OR of 1.39 (95% CI, 1,00-1.96) for melanoma risk from home use and an OR of 1.14 (95% CI, 0.80-1.61) for commercial use.

The difference in risk of home vs. commercial use can also be deduced logically. UV burns are associated with a doubling of melanoma risk (Gandini et al. II 2005), and it is logical that UV burns would be more prevalent in home use of artificial tanning devices (which are self-operated and many of which do not have maximum timer shut-off controls) than in salon use (which have trained operators and which have maximum timer shut-off controls mandated by the FDA).

The current state of the science is set forth in Colantonio et al. 2014. This comprehensive literature review examined all studies of "indoor tanning" ever done in North America, identified 8 studies as having relevant data, and did a meta-analysis of such data. Three of these 8 studies obtained and published data for home use vs. tanning salon use (Chen et al. 1998; Walter et al. 1990; Clough-Gorr 2008), and one other of these 8 studies obtained data for home use vs. tanning salon use but did not publish it (Lazovich et al. 2010). The remaining 4 studies collected data only on home use and commercial use combined, and thus showed an overall OR for melanoma risk for all locations of use combined. On top of this, Colantonio et al. 2014's meta-analysis used Chen et al 1998's OR of 1.13 (95% CI, 0.82-1.56) for conflated risk instead of Chen et al. 1998's OR of 0.79 (95% CI, 0.49-1.26) for commercial use (and did the same with respect to Walter et al. 1990 and 1999 and Clough-Gorr 2008), making it clear that Colantonio et al. 2014 showed a biased OR for combined home and commercial use, which was 1.23 (95% CI. 1.03-1.47). This says little about the risk of melanoma associated with commercial use, except that it is less than 1.23.

The results of Colantonio et al. 2014 (Fig.2) are as follows:

Study	Weight	OR used in meta-analysis	OR for home	OR for tanning salons
Chen et al. 1998	4.2%	1.13 [0.82, 1.56]	1.40 [0.97, 2.04]	0.79 [0.49, 1.26]
Clough-Gorr et al. 2008	3.5%	1.22 [0.83, 1.79]	1.39 [1.00, 1.96]	1.14 [0.80, 1.61]
Fears et al. 2011 No separate data	5.6%	0.93 [0.75, 1.79]	No separate data for home vs. salons	
Holly et al. 1995	5.3%	0.94 [0.74, 1.19]	No separate data for home vs. salons	
Lazovich et al. 2010	5.8%	1.74 [1.42, 2.13]	Separate data for home use and salon use was collected but not published	
Ting et al. 2007	2.6%	1.64 [1.01, 2.66]	No separate data for home vs. salons	
Walter et al. 1999	4.7%	1.54 [1.16, 2.04]	1.97 [1.29, 3.00]	1.16 [0.77, 1.75]
Zhang et al. 2012	6.8%	1.11 [0.97, 1.27]	No separate data for home vs. salons	
Total		1.23 [1.03, 1.47]		

Lazovich et al. 2010 did not explain why data on home use vs. commercial use was collected but not published, raising questions about the impartiality of this study particularly since the very high prevalence of "indoor tanning" (51%) indicates that most of the "indoor tanning" studied may have occurred at home.

A meta-analysis of the separated-out data in the 3 studies having such data shows the following results:

Study	OR Home	OR Salons
Chen et al. 1998	1.40 [0.97, 2.04]	0.79 [0.49, 1.26]
Clough-Gorr et al. 2008	1.39 [1.00, 1.96]	1.15 [0.80, 1.61]
Walter et al. 1999 (data in Walter et al. 1990)	1.97 [1.29, 3.00]	1.16 [0.77, 1.75]
Total	1.53 [1.23, 1.89]	1.05 [0.83, 1.32]

The conclusion is: **There is no scientific evidence that indoor tanning in commercial tanning salons increases the risk of melanoma.** However, there is substantial scientific evidence that use of tanning devices at home increases the risk of melanoma.

The CDC's website states that "California, Delaware, Hawaii, Illinois, Louisiana, Minnesota, Nevada, New Hampshire, North Carolina, Oregon, Texas, Vermont, Washington, and some cities and counties have banned indoor tanning by minors younger than 18 years." This is not technically accurate, since these states, cities and counties have banned tanning salon tanning by minors but have not banned home tanning by minors. These bans on use of tanning salons by persons under age 18 may have had the effect of driving persons under age 18 to home tanning. Used tanning beds for home tanning can be easily purchased on the internet for $500 or less. Attached as Annex II are pages appearing on Craigslist Dallas Texas when the search words tanning beds for sale were entered on April 20, 2016.

There are known health benefits of sun exposure, but overexposure can increase the risk of skin cancer. With respect to melanoma, the relationship with UV radiation is not straightforward. Sunburns have been associated with a doubling of risk, while chronic sun exposure has been associated with *reduced* risk (Gandini et al. II 2005). For example, research shows melanoma cases are less frequent in outdoor workers than indoor workers (Elwood et al. 1997). Squamous cell carcinoma (SCC) risk is also doubled by sunburns (de Vries et al. 2012) but, unlike melanoma, chronic sun exposure of very high lifetime amounts has been associated with increased risk of SCC (Kennedy et al. 2003).

Lamps in indoor tanning equipment replicate sun-based UV radiation. FDA's current exposure guidelines as set forth in the 1986 policy letter entitled, "Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products," is designed to prevent burning. We are not aware of any evidence that a person who has followed FDA's guidelines has been burned. However, consumers who use sunlamp products at home in an unregulated setting may or may not follow the exposure schedule or even limit themselves to the maximum timer interval, some sunlamp products used at home may or may not be in compliance with FDA standards. Approximately 25% of indoor tanning occurs at home or in other unregulated settings (Hillhouse et al. 2015).

Cumulative, lifetime, nonburning UV exposure has been associated with SCC, but the limited studies on

the subject indicate that SCC is associated with 20,000 to 50,000 lifetime hours of sun exposure (Kennedy et al. 2003). Indoor tanning in tanning salons adds some amount to the risk of SCC, at least theoretically, but with 30 annual sessions and each session being equivalent to approximately 20 minutes of sun exposure, the total lifetime UV exposure from indoor tanning of 150 hours (10 hours per year for 15 years of indoor tanning) is insignificant in comparison with the 20,000 hours associated with the threshold for SCC risk[1].

The purpose of indoor tanning in a commercial tanning salon is to receive a tan. A good tan provides significant protection against subsequent sunburn. The protection is provided by increased pigmentation and thickening of the epidermis (Newton-Bishop et al. 2011, Bataille et al. 2000, de Winter et al. 2001). It is common knowledge that a tanned person is much less likely to get burned outdoors than a non-tanned person. Scientific studies show that a moderate dose of UV, such as that received from a tanning bed operated in accordance with current FDA guidelines, produces a moderate tan with an SPF of 3 or 4 (Caswell et al. 2000). This means it takes three to four times as much sun exposure to burn a person with a tan as it does a person without a tan.

Burns are equally harmful at all ages, and there is currently an alarmingly-high prevalence of outdoor sunburns in the United States. According to the Centers for Disease Control and Prevention (CDC), the prevalence of sunburns in the United States increased from 32% of all adults in 1999 to 34% in 2004 (35 MMWR Weekly Report June 1, 2007 / 56(21);524-528;Table 1) and up to 50% in 2012 (36 MMWR Weekly Report May 11, 2012 / 61(18);317-322). Among adolescents aged 12-18 in 1999, 83% reported at least one sunburn in the previous summer, and 36% reported three or more sunburns in the previous summer (Geller et al. 2002).

By providing a tan, indoor tanning in a commercial tanning salon reduces the risk of sunburn, and studies show that reducing sunburn reduces the risk of melanoma. Encouraging persons to obtain their desired tan by using a sunlamp product in a tanning salon rather than at home may also ameliorate the possible higher burn risk associated with home use. The advent of tanning salons in the early 1980's may even be partially responsible for

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[1] Tierney et al. 2015 calculated, using a theoretical equation, that a median amount of indoor UV exposure (176 SED/year) for 15 years would increase the risk of SCC for a person age 55 in the Netherlands by 90%. Close examination of Tierney et al. 2015, however, reveals that the same equation shows that incidence of SCC for a person age 55 in the Netherlands is 0.004 per 100,000 as compared to 25 per 100,000 for the Dutch population as a whole, so the increased risk of SCC at age 55 resulting from 15 years of indoor UV exposure is insignificant.

the slight flattening since 2005 in the increase in melanoma incidence, which has been climbing since 1935. See Annex I attached hereto.

The specific recommendation for correcting the information

We recommend deletion of the entire section of the CDC's website titled "Indoor Tanning is not Safe" at http://www.cdc.gov/cancer/skin/basic_info/indoor_tanning.htm, and that the following section be inserted in lieu thereof:

"Indoor Tanning is Not Safe

Using a tanning bed, booth, or sunlamp to get a tan at a commercial indoor tanning salon or at home is called *indoor tanning*. Overexposure to ultraviolet (UV) radiation from the sun or indoor tanning has been linked to skin cancer, eye damage, and premature skin aging. UV burns are especially dangerous and have been linked to a doubling of the risk of all forms of skin cancer including melanoma (the deadliest type of skin cancer). Chronic sun exposure without burning has been linked to reduced risk of melanoma; outdoor workers have a lower incidence of melanoma than indoor workers. However, chronic sun exposure has been linked to increased risk of squamous cell carcinoma.

Dangers of Indoor Tanning – Home Tanning vs. Salon Tanning

Studies have shown that use of tanning devices at home increases the risk of melanoma. The same is not true for commercial tanning salons, which are regulated by the U. S. Food and Drug Administration and health agencies in various states. The increased risk associated with home tanning is thought to be related to higher risk of burning yourself when you tan at home. You should be extremely careful not to burn when using any tanning device or when out in the sun. UV burns are dangerous at any age.

Limited Protection of a Tan

You should not assume that a tan will prevent you from getting sunburned. A tan provides an SPF factor of approximately 3, which means it takes 3 times as much sun exposure to burn you than if you did not have a tan. However, an SPF of 3 will not necessarily prevent you from getting sunburned from a day at the beach. If you are planning to be outside in strong sunlight for an extended period at the beach or pool or engaging in other outdoor activities, you should apply sunscreen with an SPF of 15 or greater to prevent sunburn.

Statistics

Approximately 25% of indoor tanning occurs at home or in other unregulated settings. You should be particularly careful when using used tanning beds at home. Used tanning beds and the lamps in the beds may or may not be compliant with FDA guidelines, and the exposure times marked on such beds may or may not be compatible with the lamps in the beds. If more powerful lamps are in a used bed, you may get burned even if you follow the exposure schedule listed on the bed."

Description of how the person submitting this complaint is affected by the information error

The American Suntanning Association represents the owners of approximately 1,000 indoor tanning salons in 31 states of the U.S. The information error harms the business of indoor tanning salons by disseminating incorrect or misleading information about the risks of tanning.

The name, mailing address, telephone number and e-mail address of the person making this complaint

The person making this complaint is the American Suntanning Association, which is a trade association of indoor tanning salon owners in the United States. The mailing address, telephone number and e-mail address of the American Suntanning Association is:

American Suntanning Association
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Respectfully submitted,

American Suntanning Association

By: _____
Barton D. Bonn, President

Attachments:

Annex I – Graph of Melanoma Incidence 1935-2012

Annex II – Pages from Craigslist April 20, 2016

Annex III – Filings by ASA and ITA with FDA on March 21, 2016.

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