



June 4, 2018
Office of Science Quality
Centers for Disease Control and Prevention InfoQuality@cdc.gov

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 third bullet point under the heading "International Meta-Analyses (Combined Studies)" appearing in the section of the CDC's website titled "Indoor Tanning is Not Safe" at http://www.cdc.gov/cancer/skin/basic_info/indoor_tanning.htm, as follows:

"A 2014 study by: Wehner and colleagues (<http://www.ncbi.nlm.nih.gov/pubmed/24477278>) estimated that, if about one-third of Americans indoor tan during their lifetimes, more than 400,000 cases of skin cancer could be related to indoor tanning in the United States each year."

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

The information does not comply with OMB, HHS and CDC guidelines because it is incorrect and could harm rather than help public health.

The estimate of 400,000 cases of skin cancer that could be related to indoor tanning in the United States each year is based on only three variables: (1) the prevalence of indoor tanning in the United States, (2) the population proportional attributable risk (PPAR) for indoor tanning and skin cancer, and (3) the number of skin cancer cases in the United States each year. Wehner et al. 2014 "calculated population proportional attributable risk as $(\text{prevalence of exposure} \times [\text{RR} - 1]) / (1 + \text{prevalence of exposure} \times [\text{RR} - 1])$, where RR is relative risk based on summary relative risks for NMSC and melanoma reported in two rigorous meta-analyses published in the last year [citing Boniol et al. 2012 for the RR for melanoma and Wehner et al. 2012 for the RR's for BCC and SCC].... To calculate the 95% CIs for the population proportional attributable risks, we used the above formula with the upper and lower bounds of the 95% CIs of the prevalence of exposure that we found in this analysis." See Wehner et al. 2014 at pages 392-393. "We applied our summary ever-exposure prevalence estimates for adults in the United States (35.4%) ... to calculate the population proportional attributable risks for basal cell carcinoma, squamous cell carcinoma, and melanoma." See pages 395-396.

We have previously made a filing with the Office of Science Quality showing that the ever-exposure prevalence estimate of 35.4% for adults in the United States made in Wehner et al. 2014 is invalid. On March 25, 2016, we submitted to the Office of Science Quality a paper by leading epidemiologist Diana B. Pettiti dated January 16, 2016 stating that: "The meta-analytically derived estimate of the prevalence of ever exposure to indoor tanning for adults in the United States based on the studies identified by Wehner et al. (2014) is meaningless; the estimate of the number of skin cancers attributable to indoor tanning in the United States based on this meaningless estimate is meaningless." [Emphasis added]. In response, the CDC changed its website to state that "if about one-third of Americans indoor tan during their lifetimes, more than 400,000 cases of skin cancer could be related to indoor tanning in the United States each year." [Emphasis added]. Giving health advice to the public based on speculation and "ifs" violates CDC and HHS guidelines requiring accurate health advice to the public based on science, not speculation or assumptions. So, the first variable (the prevalence of indoor tanning in the United States) is shown to be an assumption or speculation rather than a scientifically-based estimate. We now turn to the second variable, the PPAR's and their dependence on Wehner et al. 2012.

Table 2 on page 397 of Wehner et al. 2014 shows that an RR of 1.29 was used for BCC and indoor tanning based solely on Wehner et al. 2012, which resulted in a PPAR for BCC of 9.3% (.354 prevalence x [1.29-1]) / (1 + .354 prevalence x [1.29-1]) = .10266 / (1 + .10266) = .10266 / 1.10266 = .0931. Multiplying this PPAR of .0931 by the estimated 2,630,770 yearly cases of BCC in the United States resulted in attributing 244,930 cases of BCC to ever-use of indoor tanning (.093 x 2,630,770 = 244,930).

Table 2 on page 397 of Wehner et al. 2014 shows that an RR of 1.67 was used for SCC and indoor tanning based solely on Wehner et al 2012, which resulted in a PPAR for of 19.2% (.354 prevalence x [1.67-1]) / (1 + .354 prevalence x [1.67-1]) = .23718 / (1 + .23718) = .23718 / 1.23718 = .1917. Multiplying this PPAR of .1917 by the estimated 876,923 yearly cases of SCC in the United States resulted in attributing 168,115 cases of SCC to ever-use of indoor tanning (.1917 x 876,923 = 168,115).

Table 2 on page 397 of Wehner et al. 2014 shows that an RR of 1.25 was used for CMM and indoor tanning based on Boniol et al 2012, which resulted in a PPAR for CMM of 8.1% (.354 prevalence x [1.25-1]) / (1 + .354 prevalence x [1.25-1]) = .0885 / (1 + .0885) = .0885 / 1.0885 = .0813. Multiplying this PPAR of .0813 by the estimated 76,250 yearly cases of CMM in the United States resulted in attributing 6,199 cases of CMM to ever-use of indoor tanning (.0813 x 76,250 = 6,199).

We have asked Dr. David G. Hoel, a Member of the National Academy of Medicine, to review Wehner et al. 2012. His report dated May 30, 2018 is attached hereto. Dr. Hoel's conclusion is that Wehner et al. 2012 is a seriously flawed study that should not be relied upon or cited by the CDC and that use of Wehner et al. 2012 to discourage people from using tanning salons is not without risk to the public for the reasons stated in his report. The RR's for BCC and SCC of 1.29 and 1.68 determined by Wehner et al. 2012 are invalid and should not have been used in Wehner et al. 2014. The estimate by Wehner and colleagues in Wehner et al. 2012 and Wehner et al. 2014 that "more than 400,000 cases of skin cancer could be related to indoor tanning in the United States is false. By endorsing this statement to discourage people from using tanning salons, the CDC is arguably harming the public health by driving tanning salon customers to use of tanning beds in gyms, apartments, homes, clubs and other venues where the tanning beds are self-operated and thus more likely to result in UV burns. Further, statements and actions by the CDC to discourage the public from receiving non-burning UV exposure exacerbate the currently-existing severe U.S. public health problem of inadequate sun exposure.

Science developed in the past 15 years indicates that 12% of U.S. deaths (340,000 persons per year) may be linked to inadequate sun exposure [1], inadequate UVA from sun exposure decreases circulating nitric oxide leading to hypertension and increased CVD risk [2], 25(OH)D concentrations (a marker for sun exposure) of less than 10ng/mL are correlated to a 72% increased risk of colorectal cancer [3], 25(OH)D concentrations of 19.8ng/mL vs. 27 ng/mL are correlated to a 37% increased risk of breast cancer [4], 25(OH)D concentrations of 14 ng/mL vs.

32 ng/mL are correlated to a 79% increased risk of death from breast cancer in breast cancer patients [5], 25(OH)D concentrations of less than 5 ng/mL vs. more than 20 ng/mL are correlated to a 35% increased risk of type 2 diabetes [6], serum 25(OH)D concentrations of less than 20 ng/mL vs. more than 30 ng/mL are correlated to a 64% increased risk of metabolic syndrome in the elderly [7], serum 25(OH)D concentrations of below 10 ng/mL vs. above 20 ng/mL are correlated to a 122% increased risk of Alzheimer's disease [8], serum 25(OH)D concentrations of below 12 ng/mL vs. above 20 ng/mL are correlated to a 43% increased risk of multiple sclerosis in women [9], serum 25(OH)D concentrations of less than 12 ng/mL vs. more than 12 ng/mL in early pregnancy are correlated to a 90% increased risk of multiple sclerosis in offspring [10], serum 25(OH)D concentrations in neonates and pregnant mothers at mid-gestation of less than 10 ng/mL vs. more than 20 ng/mL are correlated to a 142% increased risk of autism in offspring [11], lower vs. higher sun exposure in pregnancy is correlated to a 67% increased risk of type 1 diabetes in offspring [12], and serum 25(OH)D concentrations of less than 12 ng/mL vs. more than 12 ng/mL in women who had a genetic risk for age-related macular degeneration are correlated to a 6.7-fold increase in the risk of AMD [13]. Inadequate sun exposure has also been tied to increased risk of myopia [14], psoriasis [15] and non-alcoholic fatty liver disease [16]. Identified mediators include vitamin D, nitric oxide, dopamine and serotonin. Vitamin D supplementation has not been shown to be an adequate substitute for sun exposure. The problem of inadequate sun exposure in the United States is more severe for African-Americans than for white-skinned Americans.

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- [1] Chowdury R, Kunutsor S, Vitezova A, Oliver-Williams C, Chowdhury S, Kiefte-de-Jong JC, Khan H, Baena CP, Prabhakaran D, Hoshen MB, Feldman BS, Pan A, Johnson L, Crowe F, Hu FB, Franco OH. Vitamin D and risk of cause specific death: systematic review and meta-analysis of observational cohort and randomised intervention studies. *BMJ* 2014;348:g1903. [2] Liu D, Fernandez BO, Hamilton A, Lang NN, Gallagher JMC, Newby DE, Feelisch M, Weller RB. UVA Irradiation of Human Skin Vasodilates Arterial Vasculature and Lowers Blood Pressure Independently of Nitric Oxide Synthase. *J Invest Dermatol* 2014; 134:1839-1846.
- [3] Rebel H, der Spek CD, Salvatori D, van Leeuwen JP, Robanus-Maanday EC, de Gruijl FR. UV exposure inhibits intestinal tumor growth and progression to malignancy in intestine-specific *Apc* mutant mice kept on low vitamin D diet. *Int J Cancer* 2014; Online 29 May 2014.
- [4] Engel P, Fagherazzi G, Boutten A, Dupre T, Mesrine S, Boutron-Rualt MC, Clavel-Chapelon F. Serum 25(OH)D Vitamin D and Risk of Breast cancer: A Nested Case-Control Study from the French E3N Cohort. *Cancer Epidemiol Bio Prev* 2010; 19:2341-2350.
- [5] Mohr SB, Gorham ED, Kim J, Hofflich H, Garland CF. Meta-analysis of Vitamin D Sufficiency for Improving Survival of Patients with Breast Cancer. *Anticancer Res* 2014; 34: 1163-1166.
- [6] Afzal S, Bojesen SE, Nordestgaard BG. Low 25-Hydroxyvitamin D and Risk of Type 2 Diabetes: a Prospective Cohort Study and Metaanalysis. *Clin Chem* 2013;59:381-391.
- [7] Vitezova A, Zillikens MC, van Herpt TTW, Sijbrands EJG, Hofman A, Uitterlinden AG, Franco OH, Kiefte-de Jong JC. Vitamin D status and metabolic syndrome in the elderly: the Rotterdam Study. *Eur Journal Endocrin* 2015; 172:327-335.
- [8] Littlejohns TJ, Henley WE, Lang IA, Annweiler C, Beauchet O, Chaves PHM, Fried L, Kestenbaum GR, Kuller LH, Langa KM, Lopez OL, Kos K, Soni M, Llewellyn DJ. Vitamin D the risk of dementia and Alzheimer disease. *Neurology* 2014; 83:920-928.
- [9] Munger KL, Hongell K, Aivo J, Soilu-Hanninen M, Surcel H-M, Ascherio A. 25-Hydroxyvitamin D deficiency and risk of MS among women in the Finnish Maternity Cohort. 2017; 89:1578-1583.
- [10] Munger KL, Hongell K, Aivo J, Soilu-Hanninen M, Surcel H-M, Ascherio A. Vitamin D Status During Pregnancy and Risk of Multiple Sclerosis in Offspring of Women in the Finnish Maternity Cohort. *JAMA Neurol* 2016;73:515-519.
- [11] Vinkhuyzen AAE, Eyles DW, Burne THJ, Blanken LME, Kruithof CJ, Verhulst F, White T, Jaddoe VW, Tiemeier H, McGrath JJ. Gestational vitamin D deficiency and autism spectrum disorder. *BJPsych Open* 2017; 3:85-90.
- [12] Jacobsen R, Frederiksen P, Heitmann BL. Exposure to sunshine early in life prevented development of type 1 diabetes in Danish boys. *J Pediatr Endocrinol Metab* 2016; 19:417-424.
- [13] Millen AE, Meyers KJ, Liu Z, Engelman CD, Wallace RB, LeBlanc ES, Tinker LF, Lyengar SK, Robinson JG, Sarto GE, Mares JA. Association Between Vitamin D Status and Age-Related Macular Degeneration by Genetic Risk. *JAMA Ophthalmol* 2015; doi:10.1001/jamaophthalmol published online August 27, 2015.

- [14] French AN, Ashby RS, Morgan IG, Rose KA. Time outdoors and the prevention of myopia. *Exp Eye Res* 2013; 114:58-68.
- [15] Gisondi P, Rossini M, De Cesare A, Idolazzi L, Farini S, Beltrami G, Peris K, Girolomini G. Vitamin D status in patients with chronic plaque psoriasis. *Br J Dermatol* 2012; 166:505-510.
- [16] Gorman S, Black LJ, Feelisch M, Hart PH, Weller R. Can Skin Exposure to Sunlight Prevent Liver Inflammation? *Nutrients* 2015; 7:3219-3239.

The specific recommendation for correcting the information

The third bullet point "A 2014 study by Wehner and colleagues (<http://www.ncbi.nlm.nih.gov/pubmed/24477278>), estimated that, if about one-third of Americans indoor tan during their lifetimes, more than 400,000 cases of skin cancer could be related to indoor tanning in the United States each year." appearing in the section of the CDC's website titled "Indoor Tanning is Not Safe" under the heading "International Meta-Analyses (Combined Studies)" at http://www.cdc.gov/cancer/skin/basic_info/indoor_tanning.htm **should be deleted in its entirety.**

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 tanning salons in 31 states of the U.S. The information error harms the business of tanning salons by disseminating incorrect information about the use of tanning salons.

The name, mailing address, phone 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 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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Jackson, MI 49204
Telephone 217-294-1857
E-mail address melindanorton@hotmail.com

Respectfully submitted,
American Suntanning Association

By: /S/
Melinda Norton, President

Attachment:
"Wehner et al. 2012 Indoor Tanning and NMSC Analysis," Hoel DG, Medical University of South Carolina, May 30, 2018.