

FROM THE ACADEMY

Adverse effects of ultraviolet radiation from the use of indoor tanning equipment: Time to ban the tan

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The incidence of melanoma skin cancer is increasing rapidly, particularly among young women in the United States. Numerous studies have documented an association between the use of indoor tanning devices and an increased risk of skin cancer, especially in young women. Studies have shown that ultraviolet exposure, even in the absence of erythema or burn, results in DNA damage. Countries and regulatory bodies worldwide have recognized the health risks associated with indoor tanning. In the United States, 32 states have passed legislation to regulate the indoor tanning industry, but there is an urgent need to restrict the use of indoor tanning devices at the federal level. The Food and Drug Administration is currently reviewing the classification of these devices. For all of these reasons, the Food and Drug Administration should prohibit the use of tanning devices by minors and reclassify tanning devices to at least class II to protect the public from the preventable cancers and other adverse effects caused by ultraviolet radiation from indoor tanning. (J Am Acad Dermatol 10.1016/j.jaad.2010.11.032.)

Key words: basal cell carcinoma; DNA damage; Food and Drug Administration reclassification of indoor tanning devices; immunosuppression; indoor tanning; legislation; melanoma; photoaging; photodermatoses; radiation; regulation; skin cancer; squamous cell carcinoma; ultraviolet; ultraviolet A; ultraviolet B; vitamin D.

The incidence of melanoma and nonmelanoma skin cancer is increasing at a rapid rate, particularly among young women.^{1,2} Melanoma is the most common form of cancer among young adults aged 25 to 29 years and the

Abbreviations used:

BCC:	basal cell carcinoma
CDRH:	Center for Devices and Radiological Health
FDA:	Food and Drug Administration
IARC:	International Agency for Research on Cancer
SCC:	squamous cell carcinoma
UV:	ultraviolet

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second most common cancer in those aged 15 to 29 years.³ Numerous studies have documented the relationship between exposure to ultraviolet (UV) radiation and the development of melanoma and nonmelanoma skin cancers.⁴⁻¹¹ Specifically, UV exposure from indoor tanning devices has been shown to lead to an elevated risk of melanoma. The relative risk is even higher if tanning bed use begins before age 35 years.¹²

In 2009, the World Health Organization categorized tanning beds as carcinogenic to human beings.¹³ Multiple countries have recognized the danger posed by indoor tanning devices and have taken steps to restrict or even ban their use. Brazil has imposed a total ban on the use and sale of such devices.¹⁴ France, Germany, Austria, and the United Kingdom have banned indoor tanning for individuals younger than 18 years, whereas South Australia

has imposed a ban for those younger than 18 years and anyone with type I skin. Finland allows only certain types of devices for indoor tanning use and requires periodic inspections to ensure regulations are upheld.¹⁵⁻¹⁸ In the United States, 32 states have imposed restrictions on tanning facilities, with many limiting their use by minors.^{19,20} However, the restrictions themselves vary considerably and their enforcement is not uniform.²¹

The General and Plastic Surgery Devices Panel of the US Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) Medical Devices Advisory Committee convened a public hearing on March 25, 2010, to review and discuss the growing body of scientific information regarding the risks to the general public from intentional exposure to UV radiation through the use of tanning lamps. At the hearing American Academy of Dermatology Association and other medical societies urged the FDA to restrict the use of indoor tanning devices at the federal level.

This article summarizes the current status of tanning bed regulations, the harmful effects of UV radiation from the use of indoor tanning, the special risks posed to children and adolescents by UV exposure, the economic burden of skin cancer, the addictive nature of indoor tanning, and the tanning industry's uneven compliance with existing regulations. Finally, we report the General and Plastic Surgery Devices Panel of the FDA/CDRH Medical Devices Advisory Committee's recommendations to the FDA from that public hearing.

CLASSIFICATION OF MEDICAL DEVICES

The FDA classifies medical devices into 3 categories.²² Class I devices present minimal potential for harm and are subject to general controls to ensure safety and effectiveness of the device. Examples of general controls include manufacturer registration with the FDA, proper branding and labeling, and notification to the FDA before marketing the device. Currently, tanning beds are categorized as class I [with exemption 510(k)]. Devices with 510(k) exemption are exempt from premarket notification to demonstrate the safety and efficacy of the device, and its substantial equivalence to other devices already in the market. Tanning beds are also exempt from design controls, which require the manufacturer to establish and validate a development process, through which the design control documentation must be available for FDA review during a site inspection.^{22,23} They are, however, subject to "good manufacturing practice" requirements,²³ which indicate that the FDA requires device manufacturers to consistently meet applicable

requirements for the safety and efficacy of their products. Other devices in the class I category include tongue depressors, bedpans, and elastic bandages.

Class II devices are those deemed to require special controls, which may include special labeling requirements, mandatory performance standards, postmarket surveillance, patient registries, and development and dissemination of guidance documents. Products in this class include x-ray machines, UV lamps for dermatologic disorders, and laser surgical equipment for use in general and plastic surgery and dermatology.

Class III devices require additional information to ensure safety and effectiveness; they need premarket approval and a scientific review.²² Examples of class III devices include replacement heart valves, silicone gel-filled breast implants, and implantable cerebellar stimulators.

EFFECTS OF UV RADIATION

Mutations, DNA damage, and immunosuppression

The initial signaling event of exposure to UV radiation is damage to DNA within the epidermis. Studies have shown that both UVA and UVB radiation cause DNA damage and skin cancer, and although there is overlap, the mechanisms of action are different (Fig 1). UVB radiation induces DNA damage through its direct effect, resulting primarily in the formation of cyclobutane pyrimidine dimers.²⁴ The aggregation of those pyrimidine dimers inhibits cell replication and transcription, and causes C>T and CC>TT mutations in DNA, which can result in oncogenic transformation.^{25,26}

DNA damage induced by UVA occurs predominantly through the generation of reactive oxygen species resulting in the formation of oxidative products, which are mutagenic and lead to skin carcinogenesis (Fig 1).²⁷⁻²⁹ De Winter et al³⁰ demonstrated the formation of UV-induced cyclobutane pyrimidine dimer and up-regulation of p53 expression in skin biopsy specimens of human subjects after just one exposure of 1.2 minimal erythema dose emitted by indoor tanning lamps. A similar observation was made by Whitmore et al³¹ after first UV exposure at 70% of minimal erythema dose. It is well documented that repeated UV exposure can cause mutations in the p53 gene, leading to the formation of skin cancer.³²

A recent study sequenced the genomes of a malignant melanoma and a lymphoblastoid cell line from the same patient. Examining the genome and cell line sequences revealed C>T/G>A-based substitution and that the majority of these were

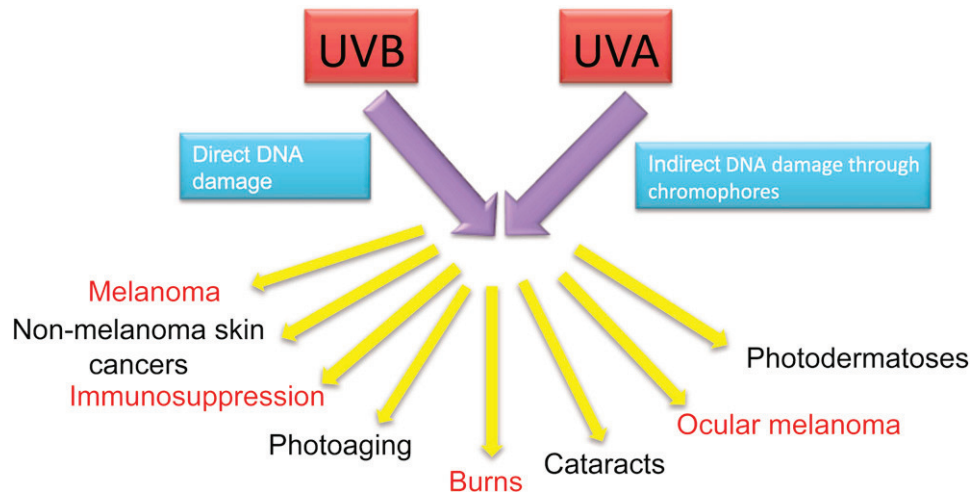


Fig 1. Effect of ultraviolet (UV) radiation on skin. UVA and UVB radiation emitted from sunlight or indoor tanning devices induces melanoma and nonmelanoma skin cancer initiated by DNA damage. UV radiation exposure can lead to immunosuppression, photoaging, erythema, burns cataracts, ocular melanoma, and photodermatoses.

CC>TT/GG>AA changes.³³ These mutations are known to be caused by DNA damage as a result of exposure to UV radiation. These signature UV-induced mutations have been observed earlier through both in vivo and in vitro studies.^{34,35} The catalog of somatic mutations identified by sequencing the cancer cell line in this study provides overwhelming evidence that exposure to UV radiation is a risk factor for skin carcinogenesis.

Cui et al³⁶ recently showed that when p53, a protein that is the most commonly mutated suppressor gene in the body, recognizes DNA damage, which then stimulates the production of pro-opiomelanocortin. Pro-opiomelanocortin, in turn, generates the release of melanocyte-stimulating hormone, which is responsible for the production of pigment, clinically manifested as tanning. The pivotal role of p53 in this process is demonstrated by the inability of mice lacking the p53 gene to tan.³⁷ Thus, DNA damage is the required first step for both pigmentation/tanning and skin carcinogenesis. The DNA damage intermediate for tanning is identical to the DNA damage intermediate that transforms a cell to produce cancer. Therefore, tanning is a form of stress response of the skin.³⁸ Studies in human beings have shown that repeated suberythemal dose exposure did not confer protection against DNA damage.^{39,40} In other words, DNA damage occurs even in the absence of UV erythema and it is clear that if there is tanning, DNA damage has occurred; hence, there is no safe tan.¹¹

In addition to photocarcinogenesis, other side effects of UV exposure include: induction and elicitation of photodermatoses such as polymorphous

light eruption, actinic prurigo, and chronic actinic dermatitis; chemical or drug-induced phototoxicity and photoallergy; exacerbation or induction of systemic and skin diseases such as systemic or discoid lupus erythematosus, dermatomyositis, xeroderma pigmentosa, and rosacea; skin dryness; pruritus; photokeratitis; cataracts; photoaging (wrinkling, uneven pigmentation, lentigines, poikiloderma of Civatte, Favre-Racouchot syndrome, dermal elastosis, pseudoscars, and colloid milium); and photoimmunosuppression (Fig 1).

Although the exact pathomechanism involved in UV-induced immunosuppression is not known, there are multiple factors that have been extensively studied. UV exposure can inhibit antigen presentation, stimulate generation of immunosuppressive cytokines, and induce regulatory T cells leading to immunotolerance.^{41,42}

OUTPUT AND RISK OF TANNING LAMPS

UV tanning devices present a significant health hazard for multiple reasons. To promote faster tanning, tanning devices have UV radiation levels that far exceed what is found in natural sunlight and have a different ratio of UVA:UVB.⁴³ A study examining the actual UVA output at 62 tanning facilities in North Carolina found the mean level to be 192 W/m², which is 4 times as much as noon sunlight in Washington, DC, during the summer (48 W/m²).⁴⁴ The UVB output was found to be twice as much in a tanning bed as compared with the sunlight at noon.

Medical UV devices are an integral part of the practice of dermatology, but there are key differences between the medical uses of UV radiation and

its emission from tanning beds. UV exposure in the context of medical treatment is closely monitored and supervised by a physician. As with any medical treatment, the risk-benefit ratio is carefully assessed by the physician before prescribing the treatment. During phototherapy or photochemotherapy (psoralen plus UVA), patients are regularly and closely evaluated for any acute or chronic side effects.⁴⁵ Furthermore, in phototherapy units, the output of UV booths is regularly measured, and adjustment to treatment protocol is made accordingly. In contrast, tanning beds are not designed to treat diseases, therefore no beneficial health effect is derived; instead, only serious risks are present. No physician supervision takes place in tanning salons, many of the operators have minimal knowledge of the potential side effects of UV, guidelines are variable and not closely followed,^{46,47} and tanning bed lamps have a variable amount of UVA and UVB.⁴⁸

UV, INDOOR TANNING, AND MELANOMA

There are multiple studies linking melanoma with the use of tanning beds. Veierod et al⁴ conducted a prospective study from 1991 through 1999 of more than 106,379 Norwegian and Swedish women that showed regular use of tanning beds more than once per month contributed to an increased risk of melanoma. Another study comparing 200 patients with melanoma with 804 control subjects showed a relative risk of 2.1 for “ever” versus “never” tanning bed use.⁴⁹ A meta-analysis of 10 studies comparing “ever” versus “never” tanning bed use showed a significant association with use of tanning beds and the later development of melanoma.⁵⁰ A survey of 1518 dermatology patients also showed an elevated risk of melanoma in those who had ever used a tanning bed, particularly if the patient was younger than 45 years and/or had tanning sessions longer than 20 minutes.⁵¹ The International Agency for Research on Cancer (IARC) conducted a meta-analysis of 7 studies that showed a relative melanoma risk of 1.75 if tanning began before the age of 35 years.¹² More recent data were published from the cohort of 106,379 Norwegian-Swedish women, this time followed up through 2005, demonstrating that the association persists into the modern tanning bed era. The data showed odds ratios of 1.5 for exposure between the ages of 30 and 39 years and 1.6 between 40 and 49 years.¹⁰

In 2009, the IARC classified UV radiation from tanning beds as “carcinogenic to humans” (group 1) based on its meta-analysis, which concluded that risk of melanoma is increased by 75% when exposure to tanning beds occurs before the age of 30 years.¹³

A concern that has been raised is whether melanoma in any individual can accurately be attributed to a tanning bed experience or exposure to sunlight outdoors. A British study that considered point estimates of the relative risk of melanoma in tanning bed users, the prevalence of tanning bed use, and the incidence of melanoma concluded that for the English population in 2004, 25% of melanomas in young women could be attributed to tanning bed use.⁵² Two newly published multicenter population-based case-control studies provided further evidence of the risk of skin cancer and the use of indoor tanning devices.^{53,54}

One of the key differences in behavior between young men and women is that women are significantly more likely to use tanning beds than men.⁵⁵ Dermatologists are now seeing more melanomas in young women and that the melanomas are appearing in sites normally hidden from sunlight but often exposed in tanning beds, such as breast and genital areas.¹ 2006 Surveillance, Epidemiology, and End Results (SEER) data indicate that there has been a significant increase in melanoma incidence among women in their early to mid-30s whereas a similar increase has not been noted in men of the same age group.^{56,57}

UV, INDOOR TANNING, AND NONMELANOMA SKIN CANCER

The annual number of nonmelanoma skin cancer cases in the United States may be as high as 3.5 million.⁵⁸ Squamous cell carcinoma (SCC), which may be associated with a risk of metastasis and death, accounts for approximately 20% of nonmelanoma skin cancers.⁵⁹ Exposure of the epidermis to UV radiation can cause p53 mutations that can lead to the development of clonal tumors and SCC.⁶⁰ The total lifetime dose of exposure to sunlight is directly related to the development of SCC.^{61,62} This is reflected by the observation that the incidence of SCC increases with age and in sun-exposed skin of chronically immunosuppressed patients. Basal cell carcinoma (BCC) is the most common cancer in human beings. It is 4 to 5 times more common than SCC, and is associated with intermittent, recreational sun exposure. BCC occurs most frequently on head and neck, indicating an association with UV exposure. UV radiation is involved in the mutation of the *hedgehog*, *PTCH*, and *GLI* intercellular signaling pathway genes, which are associated with the development of BCC.⁶³

The role of indoor tanning beds in the development of nonmelanoma skin cancer is substantiated by a study showing that those who use tanning beds

are 2.5 times more likely to develop SCC and 1.5 times more likely to develop BCC.⁹

SUNSCREEN AND NONMELANOMA SKIN CANCER

The role of UV and nonmelanoma skin cancer is further demonstrated by randomized trials conducted on sunscreen use and SCC and BCC. A randomized controlled trial conducted for 4.5 years in an Australian community evaluated the effectiveness of daily application of sun protection factor—16 broad-spectrum sunscreen use in preventing BCC and SCC. The results of this trial showed a significant decrease in the incidence of SCC but not in the incidence of BCC.⁶⁴ An 8-year follow-up study of the same participants found sunscreen to significantly decrease SCC incidence rates by 38% and decrease BCC incidence rates by 25%, although the latter decrease did not reach a statistically significant level.⁶⁵ In addition, randomized trials have shown a significant protective effect of the use of daily sunscreens against actinic keratoses, potential precursor lesions for invasive SCC.^{66,67}

THE RISKS OF INDOOR TANNING TO CHILDREN AND ADOLESCENTS

Substantial numbers of children and adolescents are using indoor tanning facilities. Studies show that 2 to 3 million annual users of indoor tanning facilities are adolescents; 24% of indoor tanners are 13 to 19 years old.⁶⁸ In a study of more than 10,000 children and adolescents, 35% of teenaged girls were found to be using tanning devices.⁶⁹

Although melanoma rarely occurs in children, UV exposure during childhood is a known risk factor for the development of melanoma.⁷⁰⁻⁷² Several studies have linked the use of tanning lamps early in life to an increased risk of melanoma later in life.^{10,69} The use of tanning beds can increase mole counts and can cause existing moles to change,⁷³ both of which are associated with increased risk of subsequent melanoma.

A survey conducted among young adults found that knowledge of limiting indoor tanning to prevent nonmelanoma and melanoma skin cancers had increased from 1988 to 1994 but that increase in knowledge did not translate into a change in behavior. An increase in indoor tanning was concurrent with the perception that tanned skin is attractive and healthy.⁷⁴ Dermatologists are seeing more young women with advanced skin cancer, with thicker tumors than previously seen in this age group. Patients with melanoma have a disproportional increased chance of a history of indoor tanning;

research has demonstrated that 71% of the 1 million persons who tan indoors each day are women.⁶

ECONOMIC BURDEN OF SKIN CANCERS

Melanoma is now the most common form of cancer in Americans in the age group 25 to 29 years. It is increasing faster for girls and women aged 15 to 29 years than in boys and men of the same age group.³ Purdue et al⁷⁵ showed that in the period from 1970 to 2008, the overall age-adjusted annual incidence of melanoma increased 1.9 times for women, compared with 1.6 times for men. Meanwhile, there has been a 27-fold increase in the use of tanning beds by young Americans between 1998 and 2007.⁷⁴

The increasing incidence of skin cancer comes at a very high cost. A study by Bickers et al⁷⁶ estimated the total, direct cost of all skin cancer in 2004 at approximately \$1.5 billion. For melanoma alone, the total annual cost of office visits, hospital charges, drugs, inpatient treatment, and emergency department visits is nearly \$300 million. Although non-melanoma skin cancers are less expensive to treat individually than melanoma or cancers of the stomach, lung, or breast, the economic burden of non-melanoma skin cancer to society is significant because of the magnitude of the case load. Because of the sheer number of these tumors, nonmelanoma skin cancers are the fifth most expensive group of tumors to treat in the Medicare population.⁷⁷

VITAMIN D: THE PSEUDOCONTROVERSY

Proponents of indoor tanning frequently claim that maximizing vitamin D levels through intentional UV exposure to the sun or indoor tanning beds helps prevent internal cancers, hypertension, multiple sclerosis, and other disorders. This approach to the indoor tanning debate asks which is the lesser of two evils: skin cancer and photoaging or cancer of the breast, prostate, and other organs. This is a false controversy. The causal association between vitamin D levels and cancer prevention has not been clearly demonstrated. There are epidemiologic studies that show a statistical relationship between lower serum vitamin D levels and a higher incidence of some of these diseases.⁷⁸⁻⁸⁰ Conversely, there are also multiple studies that have suggested an inverse association between vitamin D intake and cancer.⁸¹⁻⁸³ Further well-designed prospective studies of vitamin D intake and its association to diseases and relationship to serum 25-hydroxy vitamin D concentrations are needed to better assess this ambiguous association. What is clear is the dose-dependent association between UV exposure from tanning beds and subsequent skin cancer development.

Vitamin D synthesis and DNA damage are caused by the same wavelengths of UV radiation on the skin: UVB.⁸⁴⁻⁸⁷ A randomized controlled trial observed an increase in serum 25-hydroxyvitamin D₃ levels on exposure to UV radiation from tanning devices; the increase was dose dependent and reached a plateau after only 4 sessions. Repeated exposure did not increase vitamin D, but studies have demonstrated that repeated exposure to UV does continue to damage DNA.^{34-36,88}

To minimize cutaneous erythema, tanning lamps emit predominantly UVA. Therefore, tanning bed lamps are not an efficient source to induce vitamin D synthesis. Furthermore, although maximum levels of vitamin D photosynthesis can be achieved at a relatively low UVB exposure, DNA damage does take place whenever tanning occurs, even in the absence of erythema.^{40,89}

Finally for those with concerns about vitamin D insufficiency, serum vitamin D levels can be maintained with the use of vitamin D supplements, which are widely available and cost less than \$20 per year. They cause no damage to the skin, do not mutate epidermal DNA, and are more reliable in their effect of raising the vitamin D level in the blood.

INDOOR TANNING AND ADDICTION

A great deal of evidence points to tanning as a form of addiction.^{90,91} The addictive nature of high-intensity UVA exposure was first suggested in 1983, when Levins et al⁹² found they could induce an elevation of plasma endogenous opioids by daily exposure to UVA but not visible light. It has been demonstrated that frequent adolescent tanners are more likely to experience additional health risks such as smoking, recreational drug use, and eating disorders.⁹³ A randomized controlled trial of the opioid antagonist naltrexone conducted on young adult volunteers who frequented tanning salons found that symptoms of opiate withdrawal occurred in the frequent tanners who were given naltrexone. These symptoms were not observed in the frequent tanners who received placebo light exposure, or in the infrequent tanners.⁹⁴

Tanning dependency was also examined in the study, and it was found that difficulty quitting was more likely among those who started tanning before the age of 13 years and those who had a high frequency of tanning bed use.⁶⁸ Recently, Harrington et al⁹⁵ used a modified CAGE questionnaire to assess behaviors associated with problem tanning. They found 41% of subjects met criteria consistent with a tanning addictive disorder, and an additional 33% met criteria for problematic tanning behavior. Early age of first tanning was associated with meeting

tanning addiction criteria, and female participants in the study were found to have a higher rate of tanning addictive disorders than the male participants. Similarly, another study found that among men, indoor tanning was positively associated with symptoms of anxiety and obsessive-compulsive disorder, and among women, indoor tanning was positively associated with the use of alcohol, tobacco, and other substances.^{96,97} Therefore, in addition to the risk of skin cancer, frequent, intentional exposure to UV light may induce a compulsive desire to tan despite the knowledge of negative consequences.

LACK OF COMPLIANCE ON THE PART OF INDOOR TANNING OPERATORS

Three key factors relating to the risks associated with indoor tanning show extreme variability in practice: the radiation output of tanning devices; the level of operator knowledge and training; and the degree to which tanning operators comply with state and federal guidelines. A study of 32 tanning facilities in North Carolina found that only one facility was in complete compliance with the 21 state and federal safety regulations, and identified more than 7 infractions per facility.⁹⁸ Another North Carolina study examined whether patrons were complying with the FDA-recommended exposure schedules outlined on the tanning beds (no more than 0.75 minimal erythema dose 3 times the first week). The researchers found that 95% of patrons were not following the exposure guidelines, and about one third started well above the level of exposure suggested for chronic users. They also found excessive amounts of UV radiation emitted by many of the tanning beds.⁴⁴

Many studies have documented that tanning operators either do not know about or do not advise their customers about the potential risk of skin cancer or even sunburn. In a survey of Minnesota high school students who used tanning salons, 50% said they were not warned about potential dangers, 28% reported not being told to wear goggles, and 17% reported never using goggles.⁹⁹ A survey of tanning operators in New York found that 80% stated that one could not get skin cancer from artificial tanning and 75% said one could not get a sunburn from artificial tanning.¹⁰⁰ Another survey of tanning operators in North Carolina found that 71% never received any formal training and 3% were allowing children younger than 10 years to tan.¹⁰¹ Within the FDA database tracking injuries from medical devices, about half of the injuries reported from 1985 to 2006 resulted from UV exposure, and 36% of the UV-related injuries were attributable to user or operator noncompliance with FDA policies.¹⁰²

Many states have no regulations, but in states where indoor tanning is regulated, research shows improved rates of parental consent and accompaniment, and reduced access for minors in locations where that is restricted—but less success in preventing everyday use.²¹ Enforcement of the regulations by state or federal agencies does not occur.

GENERAL AND PLASTIC SURGERY DEVICES PANEL OF THE FDA/CDRH MEDICAL DEVICES ADVISORY COMMITTEE HEARING

On March 25, 2010, the FDA/CDRH Medical Devices Advisory Committee met to review and discuss the growing body of scientific information regarding the risks to the general public from intentional exposure to UV radiation from the use of indoor tanning devices. After 4 hours of public testimony and 1 hour of questions from the panel to the speakers who testified, the panel discussed the key issues relating to the safety of indoor tanning and whether changes to the current classification or regulatory controls of UV-emitting devices used for tanning are needed. Key findings were as follows:

- **The panel concluded unanimously that tanning lamps and tanning beds should not be class I devices.** The panel was divided on a proposed reclassification, with some recommending that tanning beds should be class III and others preferring class II, with special controls relating to age and skin type. Other special controls suggested by panel members included a registry program for tanning bed users; stronger requirements for the education, training, testing, and recertification of tanning bed operators; and a mechanism by which the tanning bed user would be required to read and accept a series of warnings about the risks of indoor tanning before the tanning bed would activate.
- **The majority of panel members favored an age restriction for tanning.** The panel agreed that for users with Fitzpatrick skin type I, tanning is neither safe nor effective. The panel also decided that individuals with a genetic or family history of skin cancer should be subject to special restrictions and education requirements before using tanning beds.
- **The panel members agreed that sunlamps and tanning beds that are UVA only, UVB only, or a mixture of both do not need to be regulated or classified separately.** The panel was in favor of a review and changes or improvements to the current FDA performance standard for sunlamp products and UV lamps intended for use in sunlamp products.^{103,104} This could affect

requirements regarding timer systems, replacement lamps, and protective eyewear. The panel paid particular attention to strengthening requirements for protective eyewear. The panel also supported the collection of data on spectral output from tanning beds; these data could be collected in the registry system discussed earlier.

- **The panel favored some form of patient disclosure and/or patient brochures.** Currently, because tanning devices are class I devices, the only labeling requirement is the label on the device. There is no requirement for a patient brochure or patient disclosure. The panel also supported more prominent posting of user disclosures or warnings, and concluded that these regulations might need to be stronger for home-use devices than for those in salons.

The panel's recommendations will be considered by the FDA, which is hoped to issue a "proposed" ruling within 1 year.

CONCLUSIONS

There is strong evidence that UV radiation from the use of indoor tanning devices causes DNA damage that can lead to the development of both melanoma and nonmelanoma skin cancers. In addition, exposure to these devices is associated with skin burns, premature aging, corneal burns, cataracts, ocular melanoma, and photodermatoses. The addictive nature of indoor tanning is well established. Young women are disproportionately frequent users of tanning devices, therefore effective skin cancer prevention will not only require targeted public education campaigns, but regulation and legislation at both the state and federal levels. Based on the compelling evidence associating indoor tanning with subsequent skin cancer risk, morbidity and mortality, and related health care expenditures, it is recommended that the FDA take action to prohibit the use of tanning devices by minors, and reclassify tanning devices from class I to at least class II.

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