Introduction to FDA's Regulation and Classification of Tanning Lamps

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List of FDA Speakers

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- Marjorie Shulman, Program Operations Staff (POS), ODE
- Sharon Miller, Office of Communication, Education and Radiation Products (OCER)

- Introduction and History
- Device Classification
- Regulation of Tanning Beds as Electronic Radiation-Emitting Products

FDA Speakers continued

Clinical, Adverse Events, and Summary Presentation

- Peter Rumm, M.D., M.P.H. Deputy Division Director, DSORD, ODE
- Ronald Kaczmarek, M.D. Medical Officer, Office of Surveillance and Biometrics, Office of Surveillance and Biometrics (OSB)
- Markham Luke, M.D., Ph.D. Clinical Deputy Director, (ODE)

* **FDA would like to especially thank Meg Watson, MPH of the Center for Disease Control and Prevention's (CDC), and the Division of Cancer Prevention and Control, which prepared several slides derived from national surveys and cancer registries that were used in the last presentation.**

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Topics To Be Covered

- Introduce the purpose of the Advisory Committee Panel Meeting
- Introduce topic of FDA regulation of Tanning Lamps as medical devices and electronic products.
- Briefly cover the history of medical device classification of tanning lamps.
- Show examples of tanning beds and lamps

Purpose of Meeting

- Discuss the current regulatory status of tanning beds and lamps
- Discuss the adequacy of the present labeling as regulated through the Sunlamp Performance Standard
- Discuss the potential risks of exposure to tanning bed UV radiation vs. the claimed health benefits.
- Discuss possible changes in tanning bed regulation by changes in regulatory status to address the potential risks

FDA Regulation of Tanning Lamps

- UV lamps meet definition of "device" at FDCA 201(h)
- A medical device is defined as an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” which is:
    - **Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in man or other animals, or**
    - **Intended to affect the structure or any function of the body of man or other animals, and**
    - **Does not achieve it primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purpose**

Medical Device Classification History of UV Lamps for Tanning

- **1982 -** Proposed Classification Class II
- **1990 -** Tanning lamps Class II to Class I
- **1994 -** Tanning lamps made Class I Exempt
- **2001 -** Tanning lamps subject to 21 CFR 878.9

Current Ultraviolet Lamp Classification for Tanning according to (CFR 878.4635)

- a) **Identification.** An ultraviolet lamp for tanning is a device that is a lamp (including fixture) intended to provide ultraviolet radiation to tan the skin. (See § 1040.20 of this chapter)
- b) **Classification.** Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

FDA Regulation of UV Lamps for Medical Usage

- UV lamps for dermatologic disorders - Were classified as Class II medical devices under 21 CFR 878.4630:

  They are identified as a device (including fixture), that is intended to provide ultraviolet radiation of the body to photoactivate a drug in the treatment of a dermatologic disorder, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug

UV radiation wavelengths

- **UVC** 180 nm to 280 nm (not in current beds or lamps)
- **UVB** 280 nm to 315 nm
- **UVA** 315 nm to 400 nm
- Most tanning beds emit primarily UVA radiation, with 1 – 10% UVB

Tanning Lamps and Beds

Tanning Lamps and Beds

UV Lamps used in Tanning Beds

High Pressure Arc Lamp

Low Pressure
Fluorescent Lamps

Conclusion

- These topics will be covered in further depth by additional speakers
- Thank you

Device Classification and Reclassification

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Preamendment vs. Postamendment Devices

The Act divided the arena of medical devices into either:

- Preamendment Devices or
- Postamendment Devices

Depending on when the devices were introduced into interstate commerce for commercial distribution

Classification of Preamendment Devices

Preamendment Devices are classified after FDA has:

- Received a recommendation from a device Classification Panel
- Published the Panel's recommendation for comment, along with a PR classifying the device; and
- Published a FR classifying the device

Reclassification of Preamendment Devices

FDA may reclassify a preamendment device:

- in a proceeding that parallels the initial classification proceeding
- based upon new information respecting a device either on FDA's own initiative or upon the petition of an interested person

Classification of Postamendment Devices

- Postamendment devices are automatically classified into Class III
- Those devices remain in Class III and require premarket approval, unless and until
  - the device is reclassified into Class I or II
  - FDA issues a SE determination
  - the device is classified into Class I or II via the Evaluation of Automatic Class III Designation (de novo review)

Reclassification of Postamendment Devices

- May be initiated by either FDA or Industry
- FDA may, for good cause shown, refer the petition to a device classification panel
- the Panel shall make a recommendation to FDA respecting approval or denial of the petition

Device Classes

A device should be placed in the lowest class whose level of control will provide reasonable assurance of safety and effectiveness

Class I - General Controls

Class II - Special Controls

Class III - Premarket Approval

Description of Classes

Class I – Mainly includes devices for which any combination of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of devices

General controls include, for example:

- prohibition against adulterated or misbranded devices

Description of Classes (continued)

- GMPs
- registration of manufacturing facilities
- listing of device types
- record keeping
- repair, replacement, refund
- banned devices

Description of Classes (continued)

Class II

1. Devices which cannot be classified into Class I because general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of such device, and
2. For which there is sufficient information to establish special controls to provide such assurance

Description of Classes (continued)

Special Controls include, for example:

- Performance Standards
- Postmarket Surveillance
- patient registries
- development and dissemination of guidelines
- tracking requirements
- recommendations and other appropriate actions

Description of Classes (continued)

Class III

1. Devices for which insufficient information exists to determine that general and specials controls are sufficient to provide reasonable assurance of the S&E of such device, and

Description of Classes (continued)

2. Such devices are
   - life sustaining and/or life supporting
   - substantial importance in preventing impairment of human health; or
   - present potential or unreasonable risk of illness or injury

Restricted Devices

- Under the provision of Section 520(e) of FD&C Act, the FDA is authorized, by regulation, to restrict the sale, distribution, or use of a device if, because of its potentiality for harmful effect or the collateral measures necessary to its use, FDA determines there cannot otherwise be reasonable assurance of its safety and effectiveness.

Restricted Devices [continued]

- A restricted device can only be sold, distributed, or used either
  - Upon the oral or written authorization by a licensed practitioner or
  - Under such other conditions specified by regulation.
- If the device is restricted to use by persons with specific training or experience in its use or by persons for use in certain facilities, FDA must determine that such a restriction is required for the safe and effective use of the device.

Restricted Devices [continued]

- Devices such as cardiac pacemakers and heart valves, for example, require a practitioner's authorization.
- Hearing aids are restricted by a regulation which limits their sale to persons who have obtained a medical evaluation of their hearing loss by a physician within six months prior to the sale of the hearing aid. The labeling of hearing aids must provide information on their use and maintenance.

Regulation of Sunlamp Products

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Objectives

- Explain FDA's role (and limitations) in the regulation of sunlamp products/ indoor tanning under Electronic Product Radiation Control Authority
- Current and proposed FDA regulations
- Role of States & Federal Trade Comm.
- Steps being taken by other regulatory bodies outside US

What prompted FDA to begin regulating sunlamp products?

- In the mid 1970s, skin burns and eye injuries were being reported to the Consumer Product Safety Commission
  - @ ~10,000 per year.
- Known hazards of exposure to UV: acute burns, skin cancer, cataracts, etc.

Regulatory History

Under Radiation Control for Health and Safety Authority:

- 1979 – publication of Sunlamp Products Performance Standard in 21 CFR 1040.20

- 1985 - FDA amended 21 CFR 1040.20 to accommodate UVA lamps

Regulatory History – continued

- 1986 – FDA published 3 policy letters to provide guidance on:
  - Warning label
  - Maximum Recommended Exposure Time calculations
  - Lamp Compatibility

FDA Requirements under Electronic Product Radiation Control Authority

Manufacturer Reporting Requirements:

- Product Reports
- Supplemental Reports
- Annual Reports
- Test Records
- Distribution Records
- Accidental Radiation Occurrences

FDA Sunlamp Products Performance Standard

Includes requirements for:

- Labeling
- User instructions
- Timer
- Replacement lamps
- Radiation emission
- Protective eyewear

Performance Standard

21 CFR 1040.20

- Limits ratio of ‘UVC’/ ‘UVB’ to 0.003
- Limits maximum exposure time based on maximum allowable erythemal-effective dose
- Timers must have +/- 10% accuracy
- ‘Panic Button’ to allow user to manually terminate radiation

Performance Standard

- Protective Eyewear
  - Spectral transmittance:
    - < 0.001 for 200nm - 320nm
    - < 0.01 for 320nm - 400 nm
- Requires labeling and user instructions
- Requires specification of compatible replacement lamps

Compatibility of lamps

- Socket/Base Design:
  - Base designs to prevent insertion of an ultraviolet lamp into general purpose lighting fixtures.
- Emission:
  - Manufacturer must provide list of suitable replacement lamps. Emission spectra must be ‘compatible’ (+/- 10% erythema-effective) in order to ensure the ‘Maximum Recommended Exposure Time’ remains valid.

User Instructions

- Directions for achieving the recommended exposure position.
- Warning that the use of other positions may result in overexposure.
- Exposure schedule
  - Initial exposure time
  - Spacing of sequential exposures
  - Maximum exposure time

Exposure Schedule - Example

SKIN TYPE	SKIN DESCRIPTION	Week 1, Session 1-3 min	Week 2, Session 4-6 min	Week 3, Session 7-9 min	MAXIMUM EXPOSURE min
1	SENSITIVE SKIN	TANNING NOT ADVISED	TANNING NOT ADVISED	TANNING NOT ADVISED	TANNING NOT ADVISED
2	LIGHT SKIN	10	15	20	30
3	NORMAL SKIN	12	18	23	30
4	DARK SKIN	15	22	27	30

Recent Activities

2007 TAN* Act

FDAAA 2007 Sec. 230:

Required FDA to determine:

- If labeling for tanning devices provides sufficient risk information
- If revised warning label better conveys risks,

OR, if

- No warning label can adequately communicate risks

*Tanning Accountability and Notification

Current Warning Label

"DANGER - Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer.

WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.

Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from the use of this product."

Alternate Warning Label used in Focus Groups

DANGER – Ultraviolet Radiation

Avoid overexposure- It may cause severe burns

Read instructions carefully

Ultraviolet Radiation causes:

- Skin Cancer
- Injury to the Eyes and Skin
- Skin Aging

WEAR PROTECTIVE EYEWEAR TO PREVENT EYE INJURY

Certain medicines or cosmetics can increase your sensitivity to ultraviolet radiation – Consult your physician before tanning

Conclusions from Focus Groups

- Modifying label would communicate the risks of indoor tanning more effectively
- Positioning could be improved by specifying the warning label be separated from other labels to highlight its importance.

Proposed Amendments to Sunlamp Product Performance Standard

- Revise content & format of warning label
- Ensure label is visible prior to use
- Revise Exposure Schedules based on current science
- Require uniform lamp code to facilitate correct replacement, reduce burns
- Add requirements on visible transmittance for protective eyewear - to protect retina

States Authority

- 30 States currently have regulations in place; some include restrictions on minors' access to tanning facilities.
  - The age restriction varies among States, i.e. 14 to 18 years of age.
- State inspectors can check for:
  - Presence of proper labeling
  - Accuracy of timer
  - Compatible lamps
  - Other, non-radiation issues, e.g. hygiene, training
- FDA provides input into Suggested State Regs

Federal Trade Commission (FTC)

The FTC has authority to protect consumers from unfair or deceptive business practices.

- 1/26/10: Indoor Tanning Association settles FTC charge that it deceived consumers about skin cancer risks from tanning *

- Ads that make claims about the safety or health benefits of indoor tanning are required to clearly and prominently make this disclosure:

"NOTICE: Exposure to ultraviolet radiation may increase the likelihood of developing skin cancer and can cause serious eye injury."

*http://www.ftc.gov/opa/2010/01/tanning.shtm

FTC - continued

- Ads that make claims that exposure to ultraviolet radiation produces vitamin D in the body must clearly and prominently make this disclosure:

"NOTICE: You do not need to become tan for your skin to make vitamin D. Exposure to ultraviolet radiation may increase the likelihood of developing skin cancer and can cause serious eye injury."

*http://www.ftc.gov/opa/2010/01/tanning.shtm

What's being done outside US

Brazil - Banned sale of sunlamp products for tanning – 11/2009

Parts of Europe and Australia

- Age restrictions, e.g. no use by minors
- No sales to minors
- No unsupervised use, e.g. coin-operated
- Requiring "Informed Consent"
- Limiting Irradiance

What's being done outside US - Standards

International Standard – IEC 60335-2-27, Ed. 5.0, 12/2009

- Similar requirements as in FDA standard, in addition:
- Tanning devices are separated into two classes:
  - Household: Intensity Limit ≈ 0.3 W/m^2 (eryth-wt'd equivalent)
  - Commercial Use; ≈ 0.6 W/m^2 (eryth-wt'd equivalent)

What's being done outside US - Standards

IEC Std. – ct'd

- Maximum dose = 600 J/m^2 (CIE Eryth. –wt'd)
- UV fluorescent lamps are req'd to be marked w/ a UV code to facilitate replacement
- Detailed measurement requirements specified
- Recommended Limit of Annual Dose = 15 kJ/m^2

European Union Std.

Very similar to IEC std, except

- Max Intensity = 0.3 W/m^2 (eryth. wt'd) for all tanning equipment
- Type Classifications are Normative
- No use by minors or skin types I & II

Summary

- FDA Performance Standard (1985) imposes requirements on manufacturer, but does not regulate use
- FDA is amending this standard
- 30 States have regulations in place which include some controls over use
- FTC has jurisdiction over advertising practices
- International/European standards are more restrictive/comprehensive and include some controls over use

Thank you!

Sun Lamps and Tanning Beds - Potential Benefits and Risks

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Presentation to
General and Plastic Surgery Advisory Committee
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FDA clinicians will review:

- Some additional background on:
  - UV radiation
  - Changes in the types of radiation in sunlamps
  - Skin types by the Fitzpatrick Scale
  - Potential risks of tanning, focusing on the risk of cancer (and in particular of melanoma)
  - Skin cancer incidence
- Potential or claimed health benefits for tanning
- Potential evidence for an increased risk, depending on age, for melanoma and some of the limitations of the current literature

Fitzpatrick Classification of Skin Types					
Skin Type	Hair	Complexion	Freckles	Sun Reaction	Tanning
I	Red or Blond	Very fair	+++	Always burns	Never tans
II	Blond	Fair	++	Often burns	Tans lightly
III	Blond or Light Brown	Fair to medium	+ to 0	Sometimes burns	Tans progressively
IV	Brown	Olive	0	Rarely burns	Tans easily
V	Brown to Black	Dark	0	Rarely burns	Tans deeply
VI	Black	Very dark	0	Never burns	Tans deeply (www.ccohs.ca)

UV Radiation and Their Features

Ultraviolet Radiation Type	General Features
Ultraviolet A radiation (UVA, long-wave UV)	-not filtered out in the atmosphere -passes through glass -produces some tanning -once considered harmless but now believed harmful over the long term -levels remain relatively constant throughout the day
Ultraviolet B radiation (UVB, sunburn radiation)	-some filtered out in the atmosphere by the ozone layer -does not pass through glass -causes sunburn, tanning, wrinkling, aging of the skin and skin cancer -highest intensity at noontime
Ultraviolet C radiation (UVC, short-wave UV)	-filtered out in the atmosphere by the ozone layer before reaching earth -major artificial sources are germicidal lamps -burns the skin and causes skin cancer (www.ccohs.ca)

Claimed benefits of Tanning

- "Minimizes the risk of sunburn while maximizing the enjoyment and benefit of having a tan.
- Teaches tanners how their particular skin type reacts to sunlight and how to avoid sunburns.
- Government-regulated controls ensure safety, consistency, and optimal exposure unlike the outdoors". (Indoor Tanning Association: http://www.theita.com/indoor/ (3/5/210)

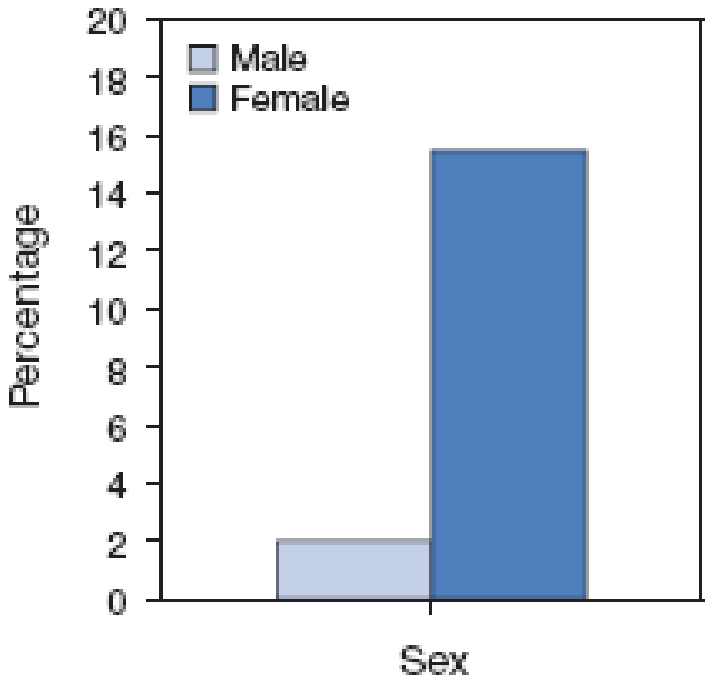
Potential Benefits of Tanning

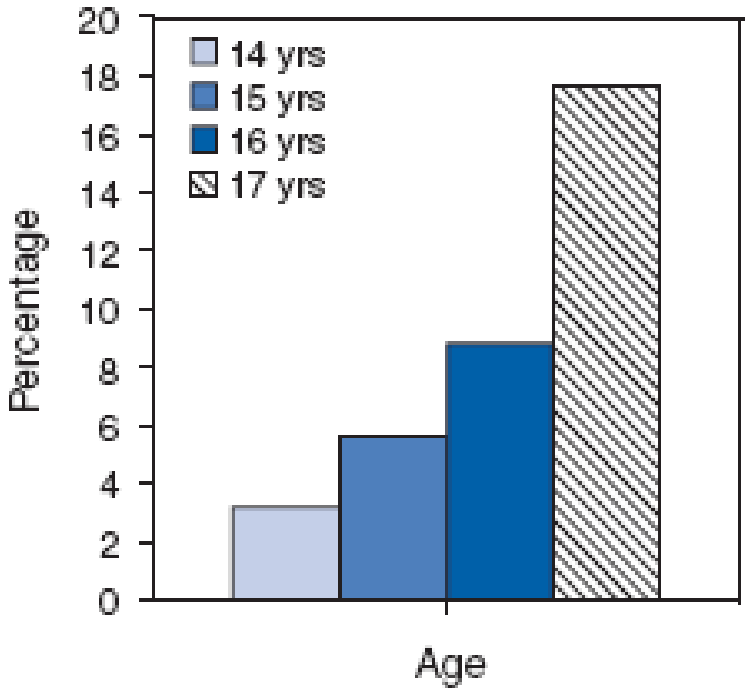
- A number of studies have suggested that youth and adults perceive a cosmetic benefit from tanning.
- Other studies have stated that the cosmetic benefit is often perceived by youth or adults to outweigh the risk.

Appearance and Risk

- Knight and co-investigators in 2002 surveyed college students (n – 489).
- 92% were aware of the risk of tanning beds.
- 47% had reported using a tanning lamp during the last year to improve their appearance. Arch Dermatol. 2002

Percentage of Teens Aged 14-17 Years Who Used Indoor Tanning Devices During the Preceding 12 Months, by Sex and Age, US, 2005*





* NHIS data. Data are based on household interviews of a sample of the civilian, noninstitutionalized population.

Possible Physiologic Effect

- Fourteen young adults who used tanning beds regularly were exposed to otherwise identical UV and non-UV tanning bed stimuli on Mondays and Wednesdays for 6 weeks. On Fridays, participants had concurrent access to the two beds.
- The majority of the adults (11/12) who came in three days a week chose the UV source for the 3rd session.
- Feldman et. al. suggested that UV light might have a physiologic effect on tanners that reinforces the usage.

J Am Acad Dermatol. 2004

Seasonal Affective Disorder

- The general therapeutic effect of light including UV light on seasonal affective disorder (SAD) has been investigated.
- Some proponents of tanning beds have suggested using tanning lamps to treat SAD or as a preventive therapy.

SAD

- Lee and co-investigators studied the spectral properties of phototherapy for SAD using a meta-analytical procedure.
- Ultraviolet (UV) waves did not seem to be essential for SAD symptom alleviation by artificial light. Acta Psychiatr Scand. 1997

SAD

- Lam and co-workers studied the effect of UV vs. non-UV light therapy in a small randomized study (n-33).
- They concluded that non-UV light therapy was just as effective for the treatment of SAD, and had a lower potential adverse effect profile. J of Seas Aff Dis 1992

Vitamin D

Vitamin D

- Vitamin D has potential positive health effects. These include increasing bone strength, preventing various cancers, reducing the risk of coronary heart disease, and/or boosting the immune system.
- There is also evidence that the U.S population has had decreased intake of Vitamin D or decreased natural production by the sun.

Vitamin D

- Vitamin D is a fat-soluble vitamin that is naturally present in very few foods, added to others, and available as a dietary supplement.
- It is also produced endogenously when ultraviolet rays from sunlight strike the skin and trigger vitamin D synthesis.

Vitamin D

- Vitamin D obtained from sun exposure, food, and supplements is biologically inert.
- It must undergo two hydroxylations in the body (liver and kidney) for activation to the form known as calcitriol to be biologically active.
- The NIH recommends (depending on age) an intake between 200-600 IU per day.

http://dietary-supplements.info.nih.gov/factsheets/vitamind.asp

Vitamin D Claims

- "Vitamin D wards off a host of debilitating and sometimes deadly diseases, including osteoporosis, hypertension, diabetes, depression, multiple sclerosis, and cancer of the bladder, breast, colon, ovary, uterus, kidney and prostate, as well as multiple myeloma and non-Hodgkin's lymphoma."

(Indoor Tanning Assocation: http://www.theita.com/indoor/ (3/5/210)

Vitamin D

- Devgun et. al. showed a moderate rise in Vitamin D levels with tanning. Br J Dermatol. 1982

- Giovannucci has claimed that vitamin D produced by tanning bed usage might help prevent 30 deaths for each one caused by skin cancer. Presentation 2005 at the American Association for Cancer Research Meeting as cited http://www.usatoday.com/news/nation/2005-05-21-doctors-sunshine-good_x.htm

WHO Position

- While sun bed use may increase vitamin D synthesis, predominantly from the UVB component, for the majority of the population, incidental exposure to the sun, combined with normal dietary intake of vitamin D, provides adequate vitamin D for a healthy body throughout the year.
- Deficiencies should be supplemented through diet rather than sun bed use.

http://www.who.int/mediacentre/factsheets/fs287/en/index.html

Vitamin D

- Lee conducted a recent meta-analysis on Vitamin D and sun lamp usage. His research suggested that the health benefits of Vitamin D do not outweigh the risk from sun lamps. Lee Dermatol Ther. 2010

Overview of risks

- The effects of UV on the eye include cataracts, pterygium (a white colored growth over the cornea) and inflammation of the eye such as photokeratitis and photo-conjunctivitis.
- Furthermore, excessive UV exposure can suppress the immune system, possibly leading to a greater risk of infectious diseases. IARC 2009 and http://www.who.int/mediacentre/factsheets/fs287/en/index.html

Overview on Risks

- Sunbeds emit predominantly UVA and some UVB , both of which can damage the DNA in cells of the skin.
- However, in recent years, lamps of sunbeds have been manufactured that produce higher levels of UVB to mimic the solar spectrum and speed the tanning process. IARC 2009 and http://www.who.int/mediacentre/factsheets/fs287/en/index.html

Medical Device Reporting

- Title 21 Code of Federal Regulations Part 803

Tanning Salons

- Tanning salons are not required to report adverse events to either the FDA or the manufacturer.
- Therefore, underreporting of adverse events is suspected with tanning bed devices.
- FDA has received nine adverse event reports since 2004.

Adverse Events with Sun Tan Booths, Product Code LEJ (n=9)

Report Sources

- Manufacturer (2)
- Voluntary (7)

Types of Events

- Serious Injury (5)
- Malfunction (2)
- Other (2)

Burns

- Cokkinides and co-investigators analyzed tanning bed usage in adolescents in two surveys (1998-2004).

- In 2534 respondents, 58% reported some type of burns due to tanning in the last year. Cancer 2004

UV: Non- Ionizing radiation

- Non-ionizing radiation is low-frequency radiation that does not have enough energy to cause ionization in tissues, but may cause adverse health consequences in other ways.
- Common types of non-ionizing radiation include ultraviolet radiation, visible light, electromagnetic fields, infrared radiation, microwaves, and radiofrequency radiation (radio waves).

UV radiation

- Among the types of non-ionizing radiation, only ultraviolet radiation has been established as a cancer-causing agent. **http://www.cancer.org**
- UV radiation may cause a number of potential mutagenic changes in cells including the formation of cyclobutane pyrimidine dimers. Kripke *Proc Natl Acad Sci* 92

UV and cancer

- The IARC Working Group in 2009 reclassified UV radiation as "carcinogenic to humans."
- UV radiation of all sources was put into Group 1 – most toxic category.

IARC 2009

UVB and potential cancer risk

- The lamps before the late 1970s produced UVB at (22-40%) and UVB radiation was thought to have the highest cancer risk.

- The percent of UVB radiation in tanning lamps was decreased to under 2.1% by the mid 1990s in most tanning lamps. Duffey and Farr 1991

Role of UVB vs. UVA in cancer

- Short-wavelength UVB (280-315 nm) has been recognized for some time as carcinogenic in experimental animals.

- However, there is an increasing body of evidence that longer-wavelength UVA (315-400 nm) also contributes to the induction of cancer.
  http://www.who.int/mediacentre/factsheets/fs287/en/index.html

Skin Cancer

- The primary health concern with the usage of tanning beds or lamps is the potential increased risk of skin cancer.

Some Potential Issues

- Individuals that use sunlamps or tanning beds, may get variable amounts of sun exposure and sun burns.
- The UV type (A and B concentrations) have changed over time in sun lamps.
- Environmental and genetic factors may affect the risk of skin cancers.
- Tanning and skin cancer risk may be affected by the Fitzpatrick skin type.
- There is a potential long lag time between any exposure to tanning lamps, and the risk of cancer formation.

Skin Cancer: SCC or BCC

- A small number of studies, primarily of the case control type and/or case series type, have suggested, but not definitely proven, a potential link between tanning bed usage and either basal cell carcinoma and squamous cell carcinoma.

- A potential risk for SCC appears to be more likely.

SCC and BCC

- Karagas and her co-authors conducted a case-control study that included 603 basal cell carcinoma (BCC) case patients, 293 squamous cell carcinoma (SCC) case patients, and 540 control subjects.

- Overall, the use of tanning devices was associated with odds ratios of 2.5 (95% confidence interval [CI] = 1.7 to 3.8) for SCC and 1.5 (95% CI = 1.1 to 2.1) for BCC.

- Adjustment for history of sunburns, sunbathing, and sun exposure did not affect the results. J Natl Cancer Inst. 2002

Melanoma

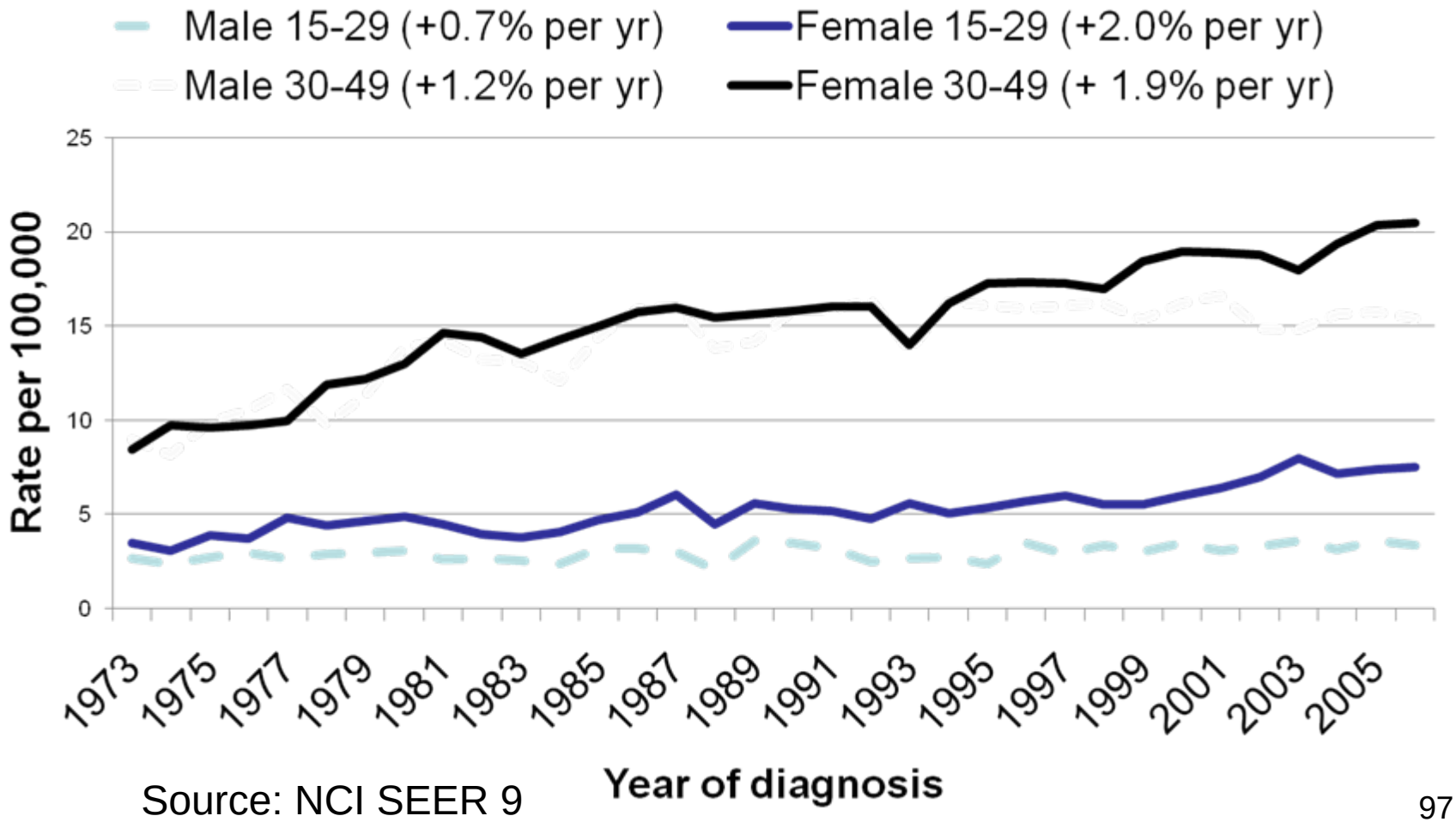
- According to the American Cancer Society, melanoma will account for about 68,720 cases of skin cancer in 2009 and most (about 8,650) of the 11,590 deaths due to skin cancer each year. www.cancer.org

Melanoma of the skin, incidence and deaths per year, United States

	Incidence		Deaths	
	Rate per 100,000	Count	Rate per 100,000	Count
All	17.9	48,216	2.7	8,014
Male	22.6	27,331	3.9	5,115
Female	14.7	20,885	1.7	2,899

Source: CDC (National Program of Cancer Registries) and NCI (SEER) combined www.cdc.gov/uscs; death data from CDC (National Center for Health Statistics)
Average annual counts and rates for 2002—2006.

Trends in melanoma incidence, age 15-49, 1973—2006



Source: NCI SEER 9

Melanoma risk

- Ting and his co-workers conducted a case control study of 1518 patients in academic dermatology studies with melanoma.
- The "ever-use" of tanning beds was found to be a significant risk factor for the development of melanoma [$P < 0.05$; odds ratio (OR), 1.64; 95% confidence interval (95% CI), 1.01-2.67]. Int J Dermatol. 2007

Melanoma risk

- Han and his co-workers conducted a nested case control study using data from the national Women's Health study in 2006.
- They reported that sunlamp usage or tanning salon attendance "was a fairly strong risk factor for melanoma after adjusting for potential confounding variables": (OR for ever vs never usage, 2.06, 95% CI 1.30-3.26). Epub 2006

Melanoma risk

- Westerdahl conducted a case control study on 571 melanoma patients and matched controls in Sweden in 2000.
- He reported a OR of 1.8 [1.2-2.7] for the "regular" use of sun lamps (vs. no use).
- Those exposed before age 36 on a "regular" basis had an OR of 4.2 [1.2-15.6 n – 42].
- He attributed most of the risk of melanoma exposure to UVA radiation. Westerdahl 2000

Meta-analysis

- It is a statistical analysis of a large collection of analysis results for the purpose of integrating the findings using identified statistical methods. *Glass 1976*

- The purpose of a pooled meta-analysis is to provide the same methodological rigor to a literature review, that is required from experimental research. http://www.stat-help.com/meta.pdf

2005 Meta-analysis

- Gallagher et. al. conducted a review of the literature from Jan 1, 1984 to April 2004 using MEDLINE.
- They identified 12 case-control studies and 1 cohort study which quantitatively evaluated the use of sunlamps and/or sun-beds and subsequent melanoma.

Meta-analysis

- Ten studies, after applying exclusion/inclusion criteria, provided pooled data for the assessment of melanoma risk among subjects who reported "ever" being exposed compared with those "never" exposed.
- Significant heterogeneity between the studies was present.
- A positive association was found between those who reported exposure and risk (summary OR, 1.25; 95% CI, 1.05-1.49).

Meta-analysis continued

- Evaluation of the metrics “first exposure as a young adult” (5 studies); and “longest duration or highest frequency of exposure” (6 studies) were also performed.
- This yielded a summary OR of 1.69; 95% CI, 1.32-2.18; and 1.61; 95% CI, 1.21-2.12, respectively.
- The authors concluded these ORs were evidence of a significant increased risk.

J Cancer Epid Biomarkers Prev 2005

Melanoma risk

- A number of published studies suggest a positive association for the development of melanoma.
- There are a small number of published studies that do not show an association.

Example of a negative association

- A multi-centre European epidemiological study of sunbed use and cutaneous melanoma in 2005 did not show an association.

- Fifty three percent of cases (597) and 57% of controls (622) reported to have ever used sunbeds The overall adjusted odds ratio (OR) was 0.90 (95% CI: 0.71-1.14). Host factors such as numbers of naevi and skin type were the strongest risk indicators for melanoma.

Study with a negative association

- The study authors, Bataille et. al., stated: “that Public health campaigns have improved knowledge regarding risk of UV-radiation for skin cancers and this may have led to recall and selection biases in both cases and controls in this study. Sunbed exposure has become increasingly prevalent over the last 20 years, especially in Northern Europe but the full impact of this exposure on skin cancers may not become apparent for many years”. Eur J Cancer 2005

Some limitations of current evidence

- The studies published are mainly case control studies.
- Potential recall bias is a major theoretical issue.
- Most studies did not study other potential confounding factors that could include:
  - Skin type
  - Other UV radiation (i.e. sun) exposure
  - Socioeconomic factors
  - Age of first use
  - Dosage of exposure to UV radiation

Limitations continued

- However, it would be hard to design prospective controlled studies, or even prospective cohort studies, due to the long lag time for cancer after exposure.
- Study populations would have to be very large to detect a difference in rare events (such as melanoma).
- There would be ethical questions about prospectively exposing patients to a known potential cancer risk.
- It would be difficult to do blinded studies.

Tanning Bed Usage and Minors

- There is FDA precedent for restricting usage of devices by age.
- As one example, breast implants for aesthetic usage are restricted according to age. (Saline at 18 y/o, Silicon at 22 y/o)

World Health Organization

- The WHO recommended to governmental policy makers in 2003 that tanning beds should not be used by anyone under the age of 18.

WHO International Commission on Non-Ionizing Radiation Protection (ICNIRP). *Health Phys* 2003.

American Academy of Dermatology

- The American Academy of Dermatology supports the WHO recommendation that minors should not use indoor tanning equipment because indoor tanning devices emit UVA and UVB radiation.

http://www.aad.org/media/background/factsheets/fact_indoortanning.html

American Academy of Pediatrics

"All children under the age of 21 should avoid the use of tanning salons and the Academy supports the efforts to ban the usage in children".

Louis Cooper, President of the AAP cited at: http://www.aap.org/advocacy/releases/safeskin.htm

IARC Meta-analysis of Sunbed Use and Skin Cancer

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IARC Meta-analysis

- Examined sunbed use and skin cancer
- Eligible studies included case-control, cohort and cross-sectional studies
- Ecological studies and case reports were ineligible

Melanoma Study Characteristics

- 19 epidemiologic studies
  - 18 case-control
  - 1 cohort
- Publication range - 1981 to 2005
- Total of 7,355 cases included in the studies employed for the meta-analysis.

IARC Meta-analysis Results Cutaneous Malignant Melanoma

Exposure	Summary RR
Ever use of indoor tanning equipment	1.15 (1.00 - 1.31)
First exposure in youth	1.75 (1.35 - 2.26)

IARC Meta-analysis Results Non-melanoma Skin Cancer

Ever use of indoor tanning equipment	Summary RR
Squamous cell carcinoma	2.25 (1.08 - 4.74)
Basal cell carcinoma	1.03 (0.56 - 1.90)

IARC Meta-analysis Limitations

- Exposure assessment
- Potential recall bias
  - almost all studies were case-control
- Potential confounding
  e.g. recreational sun exposure

Conclusions

Within the context of the aforementioned limitations:

The results of the IARC meta-analysis support the existence of an association between indoor tanning device use and the risk of cutaneous malignant melanoma, as well as squamous cell carcinoma.

Indoor Tanning – Risk-based Assessment

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Public Health Perspective

- Various governmental and non-governmental health care agencies in the U.S. and abroad have found that the known risks outweigh any potential for benefit for these UV radiation emitting device products when used for indoor tanning.

FDA Perspective

- FDA believes there is evidence for a potential increased risk for skin cancer associated with increased UV exposure (such as that achievable with exposure to UV lamps for indoor tanning).
- Adverse events associated with tanning lamps appears to be markedly under-reported.

FDA Perspective

- FDA is not aware of evidence in support of any potential health benefits associated with tanning lamps to support revision of labeling claims with regard to use.

FDA Regulation

- Currently UV lamps for tanning are regulated by FDA as both radiation-emitting electronic products and as Class I exempt devices.
- Current radiation safety regulations for these devices are in the process of being revised.
- Consideration is being given to reclassification of these devices.

Task for Advisory Panel

- The Panel will be asked to answer a series of questions related to the usage of tanning lamps to advise the agency on future regulatory action including questions that pertain to age at exposure.
- Please respond to questions based on your expert assessment and on your understanding of valid scientific evidence.

Questions for the Panel: Indoor Tanning Risk

- Based upon the evidence of risks, please identify and discuss any measures that would provide a reasonable assurance of safety and effectiveness for ultraviolet (UV) lamps for tanning, including tanning beds, related to the following:
  - Age of user/client
  - Fitzpatrick skin type of user/client
  - Genetics/Familial history of skin cancer
  - UV wavelength(s) emitted
  - Amount, Cumulative effects, Duration, Level, and/or Repetition of Exposure
  - Other(s)?

Questions for the Panel: Regulation of Tanning Lamps – Performance Standard

- Tanning lamps must comply with the FDA performance standard for "sunlamp products and ultraviolet lamps intended for use in sunlamp products" at 21 CFR 1040.20.
  - This regulation includes requirements regarding timer systems, replacement lamps, and protective eye wear, and a limit on the proportion of UVC to UVB radiation emitted.

- Please identify and discuss any recommendations for modification of any of the existing requirements of the FDA performance standard at 21 CFR 1040.20 that may address the potential risks associated with tanning lamps.

Questions for the Panel: Regulation of Tanning Lamps - Labeling

- Tanning lamps are subject to both the general labeling requirements applicable to devices at 21 CFR part 801 and the more specific labeling requirements applicable to sunlamp products at 21 CFR 1040.20.
  - For example, section 1040.20 requires tanning lamps to have a label containing a specified warning statement, recommended exposure positions, and a recommended exposure schedule, as well as user instructions that include certain information.
- Please identify and discuss any recommendations needed for labeling that may address the potential risks associated with tanning lamps such as:
  - Instructions for use
  - Patient disclosure
  - Patient brochures
  - Location(s) of labeling display:
    - in room of use and/or at the entry way
    - venue of use (e.g., use in home, health clubs, beauty spas, or tanning facilities)
    - in any promotional materials
  - Other(s)?

Questions for the Panel: Regulation of Tanning Lamps – Additional Restrictions

- Identify and discuss any measures not already discussed that may provide a reasonable assurance of the safety and effectiveness for ultraviolet lamps for tanning. These may include:
  - A signed "notice of understanding."
    - Conceptually, this would be a document explaining to the client how to use the device in order to limit the associated risks and would include a disclosure of the known potential risks associated with the use of the device.
  - A signed parental (or guardian) notice of understanding.
    - Conceptually, this would be a document explaining to the client how to use the device in order to limit associated risks and would include a disclosure of the known potential risks associated with the use of the device. Please discuss this and/or other potential restrictions on the usage of tanning beds or lamps for minors.
  - Other(s)?

Questions for the Panel: Regulation of Tanning Lamps – Medical Device Classification

- UV lamps for tanning are currently regulated as Class I devices, which means they are subject to general controls and, like most Class I devices, they are exempt from pre-market notification requirements, i.e., manufacturers do not have to submit a 510(k) to FDA prior to commercial distribution of these devices.
  - Please discuss whether a change to the current classification and associated regulatory controls for UV lamps for tanning would be needed to address the potential risks associated with UV lamps for tanning.
  - Please identify and qualify risks associated with the use of UV lamps for tanning that would require reclassification and recommend possible ways to mitigate any of the risks identified.

Questions for the Panel: Regulation of Tanning Lamps – Medical Device Classification

- Please discuss separately the risk of devices that are
  - UVA source only
  - mainly a UVB source
  - include various combinations of UVA and UVB; and

  whether such devices should be classified separately and be subject to different controls.