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Melanoma Resource Newsletter

2010-Q4-3

INDOOR TANNING PROHIBITION TO MINORS KEY FOCUS FOR FOUNDATION Legislative and Regulatory Action Update

JMNMF board members and staff testified in support of statutory and regulatory prohibitions to restrict minors from indoor tanning on the local, state and federal level throughout 2010. Significant scientific evidence that indoor tanning before the age of 30 is undeniably linked to increased risk of contracting melanoma skin cancer, coupled with statistics that melanoma is the #1 most common cancer among young adults ages 25-29; and, the #2 most common among adolescents and young adults, ages 15-29, compelled the Foundation's testimony and universal support for indoor tanning restrictions.

Currently, at least 32 states regulate or restrict the use of tanning facilities by minors having either: bans set at varying ages; or, provisions for parental accompaniment; parental permission; and, in several states, waiver for medical necessity. Of these 32 states, seven have enacted total bans, prohibiting minors under a certain age from using tanning facilities. Howard County, MD, remains the only jurisdiction in the nation, to date, to prohibit all minors (under age 18), unless a medical prescription requires treatment of a medical condition. California, Illinois, Maine, New Jersey and New York prohibit minors under age 14; Wisconsin prohibits under age 16; and, Texas prohibits minors under age 16.5. The National Conference of State Legislatures maintains a [summary database](#) of states with laws restricting minors from indoor tanning, in addition to details on 2010 and 2009 state-introduced legislation with updates on enactment or failure.

Consensus on the carcinogenic dangers of UV radiation and tanning beds is broad-based and uniform, and dramatically more compelling, as policymakers and health organizations around the globe have issued warnings and reports, regarding limited exposure and youth constraints. In June 2009, the World Health Organization's International Agency for Research on Cancer (IARC), reclassified tanning devices to their highest cancer risk category – "carcinogenic to humans." The U.S. Dept. of Health & Human Services in its 2009 Report on Carcinogens cited that exposure to sun lamps and tanning beds is "known to be a human carcinogen" and "increases the risks of malignant melanoma."

Also irrefutable and compelling, is the Federal Trade Commission's January 2010 Press Release and "Consumer Alert" regarding charges and a settlement over false health and safety claims about indoor tanning by the Indoor Tanning Association a powerful lobby group. The FTC stated that tans are signs of skin damage and that "Deliberate tanning, either indoors or out, increases your risk of melanoma and non-melanoma skin cancer." Further, according to David Vladeck, Director of the FTC's Bureau of Consumer Protection, "The messages promoted by the indoor tanning industry fly in the face of scientific evidence. The industry needs to do a better job of communicating the risks of tanning to consumers."

This overwhelming evidence, coupled with the broad misperceptions over the risk of indoor tanning by both parents and teens, provides the undergirding necessity behind much of the nationwide legislative and regulatory initiatives. In Maryland's 2010 legislative session, the Foundation joined with the – American Academy of Dermatology Association, American Cancer Society and Center for a Healthy Maryland, an affiliate of MedChi, The Maryland State Medical society – to issue a joint press release supporting legislation introduced to prohibit all minors from indoor tanning. While unsuccessful, similar legislation to further restrict existing laws



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prohibiting minors were underway, or newly proposed, in other states (nine in total), to advance the battle to protect the nation's youth .

Lastly, on the federal level, the U.S. Food and Drug Administration conducted a panel meeting earlier in 2010, of their General and Plastic Surgery Devices Panel of the Medical Devices

Advisory Committee, to review and discuss recent information, including recent literature regarding the possible risks to the general public from intentional exposure to ultraviolet radiation (UV) from use of tanning lamps. The Panel discussed the growing body of information related to the association of UV light and permanent skin changes including skin cancer. Also, the Panel was asked to recommend whether changes to current classification or current regulatory controls of UV emitting devices (lamps) used for tanning are needed. **Note:** Medical devices are assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. Currently tanning lamps/booths are Class 1 devices which is the same level assigned to tongue depressors and bandages.

Approximately four hours of public testimony was permitted by the Panel that included input from most of the major organizations at the forefront of the indoor tanning health issue (and opponents), followed by an additional hour of questions from the Panel to the public speakers before the Panel deliberated over several questions posed directly by the FDA. The JMNMF was well represented through testimony by Chairman Robert Nicolay, Board members Jane Shapiro and Gary Haynes, and staff President Greg Safko. Several of the Panel determinations and primary discussion areas during the session, included:

- Regarding the user's age, the majority of the Panel favored an age restriction for tanning.
- The Panel further decided that individuals with a genetic or family history of skin cancer should be subject to special restrictions and education requirements prior to using tanning beds.
- On the subject of tanning bed classification, the Panel's unanimous conclusion was that tanning lamps/beds should not be Class I devices.
- The Panel also recommended that the special controls could include a registry program for users of tanning beds; Other special controls proposed by the Panel included strengthened requirements for 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 Panel also endorsed the FDA's proposed use of focus groups to best determine which type of warning labels, educational materials etc. would be most effective in educating users about the risks associated with indoor tanning.
- Particular attention was paid to strengthening requirements for protective eyewear.
- Regarding labeling and additional restrictions, the Panel was in favor of patient disclosure and/or patient brochures.
- The Panel also supported more prominent posting of user disclosures or warnings.
- The Panel also reiterated its support of a system in which a tanning bed would not be switched on until the user had reviewed and accepted a series of warnings about the risks of indoor tanning.

In an early November 2010 correspondence with Mark N. Melkerson, Director of the Division of Surgical, Orthopedic, and Restorative Devices, the Foundation was informed that there was no further publicly releasable information regarding the FDA's process and, that next steps will include publication in the Federal Register of proposed rules or potential actions to permit public comment. An excerpted summary, full-text transcription of the hearing and testimonies, and copies of individual PowerPoint presentations is available on the FDA's website [here](#).



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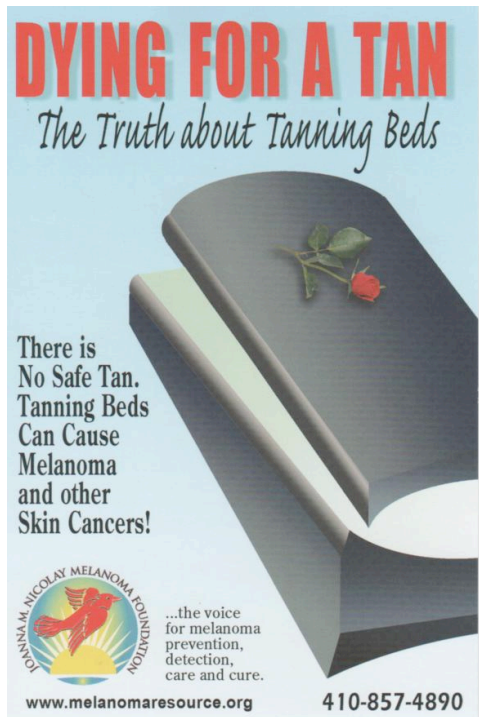
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Foundation testimony by JMNMF representatives can specifically be found on the [March 25, 2010: Meeting Transcript](#), at pages:

- 94 – Greg Safko, President
- 108 – Gary Haynes, Board member
- 123 – Robert E. Nicolay, Chairman
- 182 – Brittany Lietz-Cicala, Advisory Board member (Miss Maryland 2006)
- 189 – Jane B. Shapiro, Board member

The Foundation will keep abreast of the latest developments, as the FDA's proposed rule and actions unfold – since, the subsequent regulatory framework that can/may be introduced, will greatly impact the legislative landscape within the states nationwide.



The Foundation distributes a very straightforward educational piece on tanning beds – named “Dying for a Tan!” that was developed by JMNMF Board member Sara England, who lost her sister to melanoma caused by tanning beds. The piece provides very straightforward facts on the dangers of tanning beds – but ends with Sara’s caveat, “Designed in memory of my sister, and all those that thought tanning beds were safe.” Copies for distribution are available by contacting the Foundation:

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