FDA Panel Urges Restrictions on Tanning Beds

BY ELIZABETH MECHCATIE

GAITHERSBURG, MD. — A Food and Drug Administration advisory panel has recommended tougher restrictions on indoor tanning devices, including a ban on their use by people under age 18.

At a meeting March 25, most members of the FDA's General and Plastic Surgery Devices Panel supported such a ban as one measure to address the widespread use and potential skin cancer risks of indoor tanning. Other panelists recommended different controls to protect this age group from exposure to these devices, including required informed parental consent.

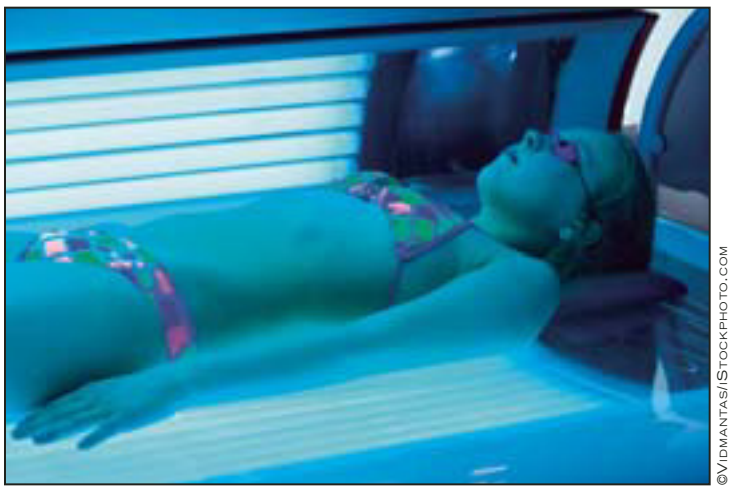
The FDA usually follows the recommendations of its advisory panels, which are not binding.

The meeting was held to discuss whether current labeling of tanning beds and lamps adequately addresses their known risks and to discuss increasing concerns about the heightened skin cancer risks associated with the devices. The advisory panel unanimously recommended moving indoor tanning devices to a higher risk category, subjecting them to more controls and requirements.

Currently, UV lamps and beds used for tanning are regulated by the FDA as class I devices, the lowest risk category. (Band-Aids are also regulated as class I devices.)

Panelists were divided between recommending reclassifying tanning devices as class II devices, which require special controls, or as class III, the highest risk category. Examples of class II devices include medical lasers and UV lamps used to treat dermatologic disorders; class III devices include breast implants and injectable cosmetic fillers.

The American Academy of Dermatology and other medical associations recommend a broad ban on the sale and use of these products for tanning, but at a minimum, the AAD says, they should be banned for use in minors under age 18.



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Most of the FDA panelists and members of the AAD support a ban on use of indoor tanning beds by people younger than 18.

Among those speaking during the public hearing portion of the meeting was the president of the AAD, Dr. William James of the University of Pennsylvania, Philadelphia, who said that dermatologists are seeing more young women with advanced skin cancer, including melanoma, who have used indoor tanning devices. The chief of the dermatology service at Memorial-Sloan Kettering, New York, Dr. Allan Halpern, testified that 25% of melanomas in young women could be attributed to UV tanning bed use.

Of the more than 1 million people per day in the United States who are exposed to UV radiation from indoor tanning devices, 70% are women, and most are aged 16-29. A total of 24% of female adolescents aged 13-19 have used a tanning bed at least once in the previous year, according to the AAD.

FDA officials at the meeting said they believe there's evidence of a potential raised risk for skin cancer associated with increased UV exposure from tanning lamps. ■

Disclosures: *Members of FDA advisory panels have been cleared of potential conflicts of interest related to the products under discussion.*

Go to www.youtube.com/ElsGlobalMedicalNews. Click on Uploads and search for James.

NEWS FROM THE FDA

New Form of OxyContin Okayed

A new formulation of OxyContin has been approved by the Food and Drug Administration in an effort to curb abuse of the widely prescribed pain-relief opioid medication.

OxyContin will be reformulated into tablets that are harder to cut, crush, break, chew, or dissolve, the FDA said. Abusers commonly break down the pills so that more of the active ingredient oxycodone is released when the drug is snorted or injected into the bloodstream, the FDA explained a written statement. The reformulation was approved April 5.

The new tablet is harder to crack, and "attempts to dissolve the tablets in liquid result in a gummy substance that cannot be drawn up into a syringe or injected," the FDA said.

The FDA is requiring the manufacturer of OxyContin, Purdue Pharma, to conduct a postmarketing study on the extent to which the new formulation actually reduces abuse of the drug.

Varicose Vein Treatment Gets Nod

Polidocanol injection was approved March 31 for treatment of varicose veins, the FDA said.

Distributed by BioFarm Medical as Asclera, polidocanol is approved to treat small spider and reticular veins up to 3 mm in diameter. The injectable agent improves the appearance of varicose veins by damaging the cell lining of the blood vessels, thus causing vessels to close and be replaced by less-visible types of tissue. Varicose veins affect half of people age 50 years and older.

Common adverse reactions to polidocanol include pain or hematoma at the injection site, bruising, irritation, and discoloration, the FDA said.

Rozerem Claims Draw Rebuke

Takeda Pharmaceuticals misrepresents its sleep aid Rozerem (ramelteon) in sales materials aimed at physicians who treat substance abusers by claiming the product has "no likelihood of abuse and no detectable toxicity," the FDA's Division of Drug Marketing, Advertising, and Communications has charged.

In a letter to Takeda's North American division, the DDMAC requested that the drug maker immediately cease dissemination of the materials.

Rozerem was approved in 2005 for use by patients whose insomnia is characterized by trouble falling asleep. It is not a controlled substance, as are competitors in the sedative-hypnotics class, but that difference alone does not "confer added safety," the DDMAC said. The FDA is particularly concerned with a bar graph in the materials that compares Rozerem with 18 hypnotic drugs on "likelihood of abuse" and "toxicity" scores, with Rozerem scoring zero. However, Rozerem is associated with "numerous risks, including potential endocrine toxicity," regulators asserted.

More Data Sought on Menthol

The tobacco industry is being asked for data about menthol cigarettes so that the FDA can determine whether the additive should be restricted or banned, agency advisers said March 31.

The FDA's new Tobacco Products Scientific Advisory Committee wants to know how the industry manufactures menthol, how and why it is added to cigarettes, and how manufacturers decide when to increase or decrease menthol levels. The committee also wants to know what the substance does in the body—including chemosensory, neurologic, and behavioral effects—and how and why menthol is marketed to certain population groups.

A number of health organizations have asked for menthol to be banned, including the American Medical Association, the American Public Health Association, the American Heart Association, and the Legacy Foundation.

The Tobacco Products Scientific Advisory Committee met for the first time since the FDA was given the power in June 2009 to regulate tobacco through the Family Smoking Prevention and Tobacco Control Act.

First Anti-Acne Lotion Approved

The first retinoid lotion for the treatment of acne vulgaris has received approval, the manufacturer announced on March 22.

Differin Lotion 0.1% (adapalene) will be available by prescription in April for treating acne on the face and body of patients aged 12 years and older.

The approval comes after positive results were seen in two similarly designed 12-week, multicenter, controlled clinical studies comparing Differin 0.1% (Galderma) to a vehicle in 2,141 acne patients.

In both studies, Differin 0.1% was shown to significantly reduce inflammatory lesions. Dryness was the most commonly reported side effect, occurring in about 7% of patients during the first 2 weeks of treatment and decreasing thereafter.

Benzoyl Peroxide Declared Safe

After 2 decades of debate, the FDA has issued a final rule declaring benzoyl peroxide to be safe and effective as an ingredient in over-the-counter topical acne products.

According to agency policy, benzoyl peroxide is now GRASE (generally recognized as safe and effective). In 1991, the FDA proposed to classify the agent as a category III agent, which meant that it needed more study. At that time, some data suggested that benzoyl peroxide was potentially carcinogenic in animals.

Subsequently, new data have allayed the agency's concerns. "We now conclude that benzoyl peroxide can be adequately labeled to minimize the risks," the FDA noted in its final rule. The new labeling will include warnings to avoid unnecessary sun exposure and wear sunscreen, to not use the product on very sensitive skin, and to keep the product away from the eyes, lips, and mouth.

—From staff reports

VERBATIM

'One of the great mysteries in stroke is the huge racial disparities in stroke mortality.'

Dr. George Howard, on the estimated 40% higher mortality from stroke in blacks, compared with whites, p. 39