POLICY & PRACTICE

CAN'T GET ENOUGH POLICY & PRACTICE? CHECK OUT OUR NEW PODCAST EACH MONDAY.
egmnblog.wordpress.com

MFDA Cites Tri-Luma Promotions

The FDA has warned Galderma Laboratories that its promotions of Tri-Luma "recommend or suggest uses . . . that have not been approved by FDA." The Tri-Luma promotions also omit and minimize risk information, said the FDA's Division of Drug Marketing, Advertising, and Communications in its 10-page letter to the company. The combination of fluocinolone acetonide, hydroquinone, and tretinoin is approved for short-term treatment of moderate to severe melasma. The company has been promoting Tri-Luma for use with glycolic acid peels, the agency said, calling it "concerning, from a safety perspective." The materials also suggest that the drug can be used in a broad range of patients for up to a year, the FDA said. Such representations are "extremely concerning from a public health perspective" and should be stopped, said the letter.

Agency Also Warns on Aczone

A journal ad for Aczone (dapsone) Gel 5% "grossly overstates" the drug's efficacy and leaves out important risk information, the FDA advertising and marketing division told drugmaker Allergan. The company is implying that Aczone substantially and quickly reduces acne lesions, when in fact, the study cited in the ad found the drug's advantage over placebo "not even nominally statistically significant," the agency said in a letter. The journal ad "presents only the study's most favorable result," said the FDA, which asked Allergan to stop running the ad.

Groups: Nano Is Sunscreen No-No

The Friends of the Earth, Consumers Union, and the International Center for Technology Assessment are warning of the dangers of nanomaterials in sunscreens. Nanoparticles, used to make titanium dioxide and zinc oxide appear clear on the skin, have not been adequately tested for safety, claim the groups. They assert that the limited data available, in fact, show that nanoparticles are more likely to enter the lungs and pass through cell membranes than normal materials are. A 2006 study found that some nanoparticles in titanium dioxide are toxic to certain marine organisms vital to the ecosystem. Consumers Union had previously found in its own testing that nanoparticles don't boost sun protection or otherwise perform better than other sunscreens. The International Center for Technology Assessment pointed out that there is no approval process for nanomaterials in any product and that labels aren't required to reveal their presence. The report is available at www.foe.org/nano-sunscreens not-worth-risk.

Device Director Resigns

Dr. Daniel Schultz, the beleaguered director of the FDA's Center for Devices and Radiological Health, has resigned from the agency. According to The Gray Sheet (a sister publication to SKIN & ALLERGY NEWS), Dr. Schultz submitted his resignation to FDA Commissioner Margaret Hamburg after they agreed that his departure "would be in the best interest of the center and the agency." The devices division has been under fire for about a year since internal whistleblowers alleged corruption in a letter to Congress and then repeated many of the charges in a January letter to President Obama. At press time, no replacement had been named for Dr. Schultz, who had directed the center since 2004.

More Faux-Botox Arrests

In yet another case involving counterfeit Botox, a Washington state beauty salon owner was arrested in late August on charges of having injected patients with fake botulinum toxin and fake Restylane (hyaluronic acid). The injections began in 2004 and continued despite the fact that the woman arrested was issued a cease and desist order in 2006. One woman had to seek care from a dermatologist after the supposed Restylane was injected into her face. According to the investigators, the vial had Chinese characters on it. Another woman had to be treated by a plastic surgeon. If convicted, the salon owner faces from 3 to 15 years in prison. The arrest was the result of a joint investigation between the Food and Drug Administration Office of Criminal Investigations and the

Immigration and Customs Enforcement Agency.

HHS Issues New HIPAA Rules

The federal government is requiring physicians and other entities covered under the Health Insurance Portability and Accountability Act to notify individuals when their health information has been breached. Under the rule going into effect this month, physicians will have up to 60 days to notify a patient when that person's health information has been accessed by an unauthorized party. If the breach involves more than 500 individuals, the Department of Health and Human Services and at least one major media outlet must be notified. "These protections will be a cornerstone of maintaining consumer trust as we move forward with meaningful use of electronic health records and electronic exchange of health information," said Robinsue Frohboese, acting director of the Office of Civil Rights at HHS. But there are exceptions to the rule: Notifications are not necessary if the information that was disclosed is unlikely to be retained. For example, if a nurse gives a patient the wrong discharge papers but quickly takes them back, it's reasonable to assume that the patient could not have retained that protected information, according to HHS. More information is available at www.hhs.gov/ocr/privacy.

Supplement Maker Fined $70 M

In a case brought by the Federal Trade Commission, a marketing group that used infomercials to tout calcium and herbal supplements as effective treatments for cancer, Parkinson's disease, heart disease, and autoimmune conditions has been ordered to pay about $70 million in consumer refunds. Last year, the U.S. District Court for the District of Massachusetts ruled that the companies and individuals involved in marketing the supplements had falsely represented their safety and efficacy. Judge George O'Toole considered potential financial penalties separately, and has now ordered the restitution in order to strip from the defendants all profits derived from the supplement sales. He also issued injunctions to prevent the defendants from making similar claims about other products.

—Alicia Ault