

'Donda West Act' Becomes Law in California

BY DAMIAN McNAMARA

PHOENIX — California Governor Arnold Schwarzenegger signed a bill into law that raises public awareness about the risks of cosmetic surgery and targets the aggressive marketing of services that make the risks “seem almost nonexistent,” California State Assemblywoman Wilmer Amina Carter said.

Known also as the “Donda West Act,”

the law is named after Kanye West’s mother, who died of complications following liposuction and mammoplasty. The law requires a physical examination 30 days before a patient undergoes a cosmetic surgery procedure.

“People may think they are well enough for cosmetic surgery, but [they] are not always,” said Ms. Carter, who introduced the legislation, known officially as AB 1116. She spoke at the joint an-

nual meeting of American Society for Dermatologic Surgery (ASDS) and the American Society of Cosmetic Dermatology & Aesthetic Surgery.

Earlier this year the governor vetoed a second patient safety bill also sponsored by Ms. Carter. That legislation would have increased enforcement of patient safety laws specifically addressing medi-spa-based cosmetic procedures and laser hair removal retail chains.

“The bill made it through with only one ‘no’ vote before Governor Schwarzenegger vetoed it,” said Dr. Robert A. Weiss, a private practice dermatologist in Hunt Valley, Md.

“We’re having budgetary issues in California, as are most states. The Governor is very adamant about getting things done, and is holding some bills hostage to get things he wants done,” Ms. Carter, who introduced the bill to the assembly, said. “It is not the fault of the bill—it’s relevant.”

Known as AB 252, the bill aimed to increase penalties and enforcement related to existing California law that prohibits corporate medi-spas and hair removal chains from hiring medical directors who provide supervision in name only. If it had become law, the Medical Board of California would be authorized to re-

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move the medical license of any physician who allowed his or her license to be used for a nonphysician to establish a medi-spa, commonly known as a “rent-a-doc” scheme. The ASDS and CalDerm co-sponsored the bill.

“There is a growing trend for elective cosmetic surgery but the public is not always aware of the risks,” Ms. Carter said. She cited the case of a patient treated at a medi-spa located on an upper floor of a mall. Something went wrong, and there was no doctor on site. Ambulance workers could not get the patient down through the mall and the patient had to be lowered through a window. “It’s those kinds of things we have to protect patients from.”

“When I became an elected official, I decided one of my goals was to author legislation to protect our citizens from harm,” Ms. Carter said. She vowed to continue working on patient safety issues. ■

2010 Travel Health Book Is Now Online

The 2010 edition of the Centers for Disease Control and Prevention’s “Yellow Book” on health information for international travelers is now available on-line (www.cdc.gov/travel) and in hard copy. Published by Elsevier, the book, which always has a yellow cover, includes information on topics ranging from jet lag, cruise ship travel, and international adoptions to respiratory conditions, drug-vaccine interactions, and persistent travelers’ diarrhea. Some topics such as medical tourism are appearing for the first time. More information can be obtained from www.us.elsevierhealth.com. ■

METROGEL®

(metronidazole gel), 1%
BRIEF SUMMARY

For topical use only. Not for oral, ophthalmic or intravaginal use.

INDICATIONS AND USAGE

METROGEL® (metronidazole gel), 1% is indicated for the topical treatment of inflammatory lesions of rosacea.

CONTRAINDICATIONS

METROGEL® (metronidazole gel), 1% is contraindicated in those patients with a history of hypersensitivity to metronidazole or to any other ingredient in this formulation.

PRECAUTIONS

General: Topical metronidazole has been reported to cause tearing of the eyes. Therefore, contact with the eyes should be avoided. If a reaction suggesting local skin irritation occurs, patients should be directed to use the medication less often or discontinue use. Metronidazole is a nitroimidazole and should be used with care in patients with evidence of, or history of, blood dyscrasia.

Information for Patients: Patients using METROGEL® (metronidazole gel), 1% should receive the following information and instructions:

1. This medication is to be used as directed.
2. It is for external use only.
3. Avoid contact with the eyes.
4. Cleanse affected area(s) before applying METROGEL® (metronidazole gel), 1%.
5. This medication should not be used for any other condition than that for which it is prescribed.
6. Patients should report any adverse reaction to their physicians.

Drug Interaction: Oral metronidazole has been reported to potentiate the anticoagulant effect of coumarin and warfarin, resulting in a prolongation of prothrombin time. Drug interactions should be kept in mind when METROGEL® (metronidazole gel), 1% is prescribed for patients who are receiving anticoagulant treatment, although they are less likely to occur with topical metronidazole administration because of low absorption.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Metronidazole has shown evidence of carcinogenic activity in a number of studies involving chronic, oral administration in mice and rats, but not in studies involving hamsters.

In several long-term studies in mice, oral doses of approximately 225 mg/m²/day or greater (approximately 37 times the human topical dose on a mg/m² basis) were associated with an increase in pulmonary tumors and lymphomas. Several long-term oral studies in the rat have shown statistically significant increases in mammary and hepatic tumors at doses >885 mg/m²/day (144 times the human dose).

Metronidazole has shown evidence of mutagenic activity in several *in vitro* bacterial assay systems. In addition, a dose-related increase in the frequency of micronuclei was observed in mice after intraperitoneal injections. An increase in chromosomal aberrations in peripheral blood lymphocytes was reported in patients with Crohn’s disease who were treated with 200 to 1200 mg/day of metronidazole for 1 to 24 months. However, in another study, no increase in chromosomal aberrations in circulating lymphocytes was observed in patients with Crohn’s disease treated with the drug for 8 months.

In one published study, using albino hairless mice, intraperitoneal administration of metronidazole at a dose of 45 mg/m²/day (approximately 7 times the human topical dose on a mg/m² basis) was associated with an increase in ultraviolet radiation-induced skin carcinogenesis. Neither dermal carcinogenicity nor photocarcinogenicity studies have been performed with METROGEL® (metronidazole gel), 1% or any marketed metronidazole formulations.

Pregnancy: Teratogenic Effects: Pregnancy Category B. There are no adequate and well-controlled studies with the use of METROGEL® (metronidazole gel), 1% in pregnant women.

Metronidazole crosses the placental barrier and enters the fetal circulation rapidly. No fetotoxicity was observed after oral administration of metronidazole in rats or mice at 200 and 20 times, respectively, the expected clinical dose. However, oral metronidazole has shown carcinogenic activity in rodents. Because animal reproduction studies are not always predictive of human response, METROGEL® (metronidazole gel), 1% should be used during pregnancy only if clearly needed.

Nursing Mothers: After oral administration, metronidazole is secreted in breast milk in concentrations similar to those found in the plasma. Even though blood levels taken after topical metronidazole application are significantly lower than those achieved after oral metronidazole, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother and the risk to the infant.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: While specific clinical trials in the geriatric population have not been conducted, sixty-six patients aged 65 years and older treated with METROGEL® (metronidazole gel), 1% over ten weeks showed comparable safety and efficacy as compared to the general study population.

ADVERSE REACTIONS

In a controlled clinical trial, 557 patients used METROGEL® (metronidazole gel), 1% and 189 patients used the gel vehicle once daily. The following table summarizes adverse reactions that occur at a rate of ≥ 1% in the clinical trials:

System Organ Class/Preferred Term	Metronidazole Gel, 1% N= 557	Gel Vehicle N=189
Patients with at least one AE	186 (33.4)	51 (27.0)
Infections and infestations	76 (13.6)	28 (14.8)
Bronchitis	6 (1.1)	3 (1.6)
Influenza	8 (1.4)	1 (0.5)
Nasopharyngitis	17 (3.1)	8 (4.2)
Sinusitis	8 (1.4)	3 (1.6)
Upper respiratory tract infection	14 (2.5)	4 (2.1)
Urinary tract infection	6 (1.1)	1 (0.5)
Vaginal mycosis	1 (0.2)	2 (1.1)
Musculoskeletal and connective tissue disorders	19 (3.4)	5 (2.6)
Back pain	3 (0.5)	2 (1.1)
Neoplasms	4 (0.7)	2 (1.1)
Basal cell carcinoma	1 (0.2)	2 (1.1)
Nervous system disorders	18 (3.2)	3 (1.6)
Headache	12 (2.2)	1 (0.5)
Respiratory, thoracic and mediastinal disorders	22 (3.9)	5 (2.6)
Nasal congestion	6 (1.1)	3 (1.6)
Skin and subcutaneous tissue disorders	36 (6.5)	12 (6.3)
Contact dermatitis	7 (1.3)	1 (0.5)
Dry skin	6 (1.1)	3 (1.6)
Vascular disorders	8 (1.4)	1 (0.5)
Hypertension	6 (1.1)	1 (0.5)

The following table summarizes the highest scores of local cutaneous signs and symptoms of irritation that were worse than baseline:

	Metronidazole Gel, 1% N= 544	Gel Vehicle N=184
Sign/Symptom		
Dryness	138 (25.4)	63 (34.2)
Mild	93 (17.1)	41 (22.3)
Moderate	42 (7.7)	20 (10.9)
Severe	3 (0.6)	2 (1.1)
Scaling	134 (24.6)	60 (32.6)
Mild	88 (16.2)	32 (17.4)
Moderate	43 (7.9)	27 (14.7)
Severe	3 (0.6)	1 (0.5)
Pruritus	86 (15.8)	35 (19.0)
Mild	53 (9.7)	21 (11.4)
Moderate	27 (5.0)	13 (7.1)
Severe	6 (1.1)	1 (0.5)
Stinging/burning	56 (10.3)	28 (15.2)
Mild	39 (7.2)	18 (9.8)
Moderate	7 (1.3)	9 (4.9)
Severe	10 (1.8)	1 (0.5)

The following additional adverse experiences have been reported with the topical use of metronidazole: skin irritation, transient redness, metallic taste, tingling or numbness of extremities, and nausea.

OVERDOSAGE: There are no reported human experiences with overdosage of METROGEL® (metronidazole gel), 1%. Topically applied metronidazole can be absorbed in sufficient amount to produce systemic effects.

DOSSAGE AND ADMINISTRATION: Areas to be treated should be cleansed before application of METROGEL® (metronidazole gel), 1%. Apply and rub in a thin film of METROGEL® (metronidazole gel), 1% once daily to entire affected area(s). Patients may use cosmetics after application of METROGEL® (metronidazole gel), 1%.

HOW SUPPLIED: METROGEL® (metronidazole gel), 1% is supplied as follows:

60 gram tube – NDC 0299-3820-60

60 gram tube with complimentary 4 oz Cetaphil® Gentle Skin Cleanser – NDC 0299-3820-04

Keep out of the reach of children.

Storage Conditions: Store at controlled room temperature: 20° to 25°C (68° to 77°F), excursions permitted between 59° and 86°F (15°-30°C).

Prescribing Information as of February 2007.

Rx Only
US Patent No. 6,881,726

Manufactured by:
Galderma Production Canada Inc.
Baie d’Urfé, QC, H9X 3S4 Canada
Made in Canada.

Marketed by:
Galderma Laboratories, L.P.
Fort Worth, Texas 76177 USA
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