**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 “seem almost nonexistent,” California State Assemblywoman Wilmer A. 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 annual 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 chains.

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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 authorize legislation to protect our citizens from harm,” Ms. Carter said. She vowed to continue working on patient safety issues.

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

**Rx Only**

**Signs/ Symptoms**

<table>
<thead>
<tr>
<th>Metronidazole Gel</th>
<th>Gel Vehicle</th>
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<td>No. 544</td>
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**Dosage**

- **Nasal**
  - **No. 544**
    - **No. 144**

**ADVERSE REACTIONS**

While specific clinical trials in the geriatric population have not been conducted, sixty-six patients ≥ 65 years old and thirty patients ≥ 75 years old 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 200 to 600 mg/day for 3 months.

Several long-term oral studies in the rat have shown statistically significant increases in mammary and hepatic tumors at doses of 45 to 450 mg/kg (71 to 714 mg/m2/day) after a single intraperitoneal injection. An increase in chromosomal aberrations in peripheral blood lymphocytes was observed in patients with Crohn’s disease who were treated with 200 to 1000 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 6 months.

In one patient study, using albino hairless mice, intraperitoneal administration of metronidazole at a dose of 45 mg/day (0.07 mg/m2/day) was 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 of 45 to 450 mg/kg (71 to 714 mg/m2/day) after a single intraperitoneal injection. An increase in chromosomal aberrations in peripheral blood lymphocytes was observed in patients with Crohn’s disease who were treated with 200 to 1000 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 6 months.

**Teratogenic Effects:** Pregnancy Category B. There are no adequate and well-controlled studies with the topical use of metronidazole in pregnant women. Metronidazole has shown evidence of carcinogenic activity in rats and mice. In one published study, using albino hairless mice, intraperitoneal administration of metronidazole at a dose of 45 mg/m2/day (144 mg/kg) was associated with an increase in pulmonary tumors and lymphomas.

Topically applied metronidazole can be absorbed in sufficient amount to produce systemic effects.

**Drug Interactions:** Intramuscular administration of metronidazole in a dose of 45 mg/m2/day (approximately 77 mg/kg) for 1 week increased the frequency of micronuclei in mice after intraperitoneal injections. An increase in micronuclei in peripheral blood lymphocytes has been reported in patients with Crohn’s disease who were treated with 200 to 1000 mg/day of metronidazole for 1 to 24 months. However, in another study, no increase in micronuclei in peripheral blood lymphocytes was observed in patients with Crohn’s disease treated with the drug for 6 months.

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