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class action litigation alert

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Venable's Los Angeles Office Secures Preemption Victory in California Medical Device Consumer Class Action at the Ninth Circuit.

In a ruling issued on September 28, 2011, the United States Court of Appeals for the Ninth Circuit held that federal law preempted California consumer class action claims against the manufacturer of a contact lens cleaning solution because those claims would have required the manufacturer to conduct premarket testing beyond that required by the FDA. *Degelmann v. Advanced Medical Optics, Inc.*, __ F.3d. __, 2011 WL 4470641 (9th Cir. Sept. 28, 2011).

The defendant in *Degelmann* had marketed its contact lens solution as an effective contact lens disinfectant. *Id.* at *1. The plaintiffs alleged that the defendant's solution was less effective than other solutions at disinfecting lenses from one specific type of microorganism, Acanthamoeba, and therefore labeling the product as a "disinfectant" violated California's Unfair Competition Law and False Advertising Law. *Id.*

The Ninth Circuit ruled that federal law preempted plaintiffs' claims. The court noted that the FDA regulates contact lens cleaning solutions as medical devices, and that the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") preempt some state and local causes of action regarding medical devices. *Id.* at *3. Specifically, the MDA provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under [the FDCA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Id. (quoting 21 U.S.C. § 360k(a)). The court reasoned that this statute preempts state law claims when there is "(1) a federal requirement imposed on the device under the FDCA, and (2) the challenged state or local rule must impose a requirement that is different from, or adds additional obligations to, the federal requirements." *Id.* at *3.

Contact lens cleaning solutions are "Class II" medical devices under the MDA, which means that they must meet FDA "special controls" in order to be cleared by the FDA for sale in the United States. *Id.* at *3. The FDA's "special controls" for lens solutions are contained in an FDA guidance document: *Guidance for Industry: Premarket Notification (510(k)), Guidance Document for Contact Lens Care Products* (1997) ("Guidance Document").

The Guidance Document provides that "[i]n order for a contact lens care solution to be labeled as a contact lens 'disinfecting solution,'" the product "should meet the primary performance criteria of the [Guidance Document's disinfectant testing] procedure for contact lens disinfecting products." *Id.* at *4. (quoting Guidance Document). These performance criteria require solutions to show a prescribed level of efficacy in killing five representative microorganisms: Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Candida albicans, and Aspergillus niger. *Id.* However, the criteria do not require a solution to demonstrate efficacy at killing Acanthamoeba. *Id.*

The court noted that it was undisputed that the defendant's solution met the performance criteria for killing the five microorganisms listed in the FDA Guidance Document, and therefore, "with regard to the labeling at issue in this lawsuit, the FDA has promulgated specific requirements, which [defendant's product] met." *Id.* at *4. The court then found that in order for plaintiffs to recover, the court would have to rule that California law "required something different than what the FDA required in order for [defendant] to label [the product] as a disinfectant." *Id.* Specifically, under plaintiffs' theory the court would have to find that California law "required that [defendant] test for Acanthamoeba, and show that [the product] kills it in sufficient quantities. That is, California law would have a requirement that is additional to the federal requirements." *Id.* Because plaintiffs' claims would have placed such additional requirements on defendant, the court concluded that the "claims are expressly preempted by § 360." *Id.* at *5.

Ben Whitwell and **Christopher Williams**, both of Venable LLP's Los Angeles office, represented the defendant in this case.

For a copy of the Ninth Circuit's opinion, click **here**.

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