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BLOG

Eleventh Circuit Affirms CoolSculpting Device Manufacturer Win on Warning and Defect Claims

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In a recent decision, the Eleventh Circuit affirmed the summary judgment victory of Zeltiq Aesthetics, Inc. in a failure-to-warn and design defect lawsuit regarding its CoolSculpting medical device and found that a health care provider's misunderstanding of an adverse effect did not bear on the adequacy of the product's warning.

As summarized in the Court's decision, Zeltiq's CoolSculpting machine applies cold to fat in order to destroy fat cells in a process called "cryolipolysis." *Cates v. Zeltiq Aesthetics, Inc.*, 73 F.4th 1342, 2023 WL 4671283 (11th Cir. July 21, 2023). Zeltiq has included warnings, including in its device manual and training sessions, that CoolSculpting patients may develop an adverse effect known as paradoxical adipose hyperplasia (PAH). This adverse effect causes patients to experience an enlargement rather than a reduction of fat. *Id.* at *1–2. Zeltiq has recently faced a wave of lawsuits regarding the adequacy of the PAH warning for its CoolSculpting machines.

Here, Plaintiff received multiple cycles of CoolSculpting from a nurse practitioner who performed the treatment under the supervision of a doctor. *Id.* at *2. Plaintiff later developed PAH, and surgeons recommended liposuction to treat it. *Id.* The nurse practitioner allegedly never warned Plaintiff of the potential PAH side effect, but stated she knew it was one. She additionally testified that she believed patients who did not follow post-treatment care were more likely to experience PAH, even though this is an incorrect assumption. *Id.* at *2–5. Further, Plaintiff signed a consent form that included a warning of PAH as a "rare side effect." *Id.* at *2. The nurse practitioner testified that she also considered the side effect rare in her experience, finding it "had occurred a handful of times in the 2,000 to 4,000 CoolSculpting procedures she had performed." *Id.*

Plaintiff sued Zeltiq in Florida under failure-to-warn and design defect theories. In assessing failure-to-warn cases, Florida follows the learned-intermediary doctrine. Thus, under that doctrine, Zeltiq owed a duty to warn the medical professionals of the CoolSculpting device's adverse effects rather than Plaintiff (or any other patient). *Id.* at *3–4. As the Court observed, the adequacy of a warning under Florida law can also "be resolved as 'a question of law where the warning is accurate, clear, and unambiguous.'" *Id.* at *4. Further, "[a] warning is adequate as a matter of law when it 'make[s] apparent the potential harmful consequences' of the product." *Id.* And lastly, Florida assesses adequacy in light of how a reasonable practitioner would understand the warning. *Id.*

The district court granted summary judgment in favor of Zeltiq, finding that Zeltiq's warnings about PAH were adequate as a matter of law, and that Plaintiff had failed to provide any expert testimony establishing that the PAH

risk associated with CoolSculpting outweighed the product's utility. *Id.* at *1. On appeal, Plaintiff argued that Zeltiq's PAH warnings were insufficient because "(1) the warnings fail to accurately reflect the 'severity of the risk,' and (2) the warnings were insufficient to warn [the] Nurse Practitioner [] given her alleged misunderstanding of PAH." *Id.* at *4. Specifically, with respect to severity, Plaintiff argued that PAH is a "fibroplasia," which is more severe than the product manual describes. *Id.* Plaintiff also contended that the nurse practitioner's erroneous understanding of PAH (i.e., thinking it is more likely with improper post-treatment care) was "evidence that Zeltiq's warnings were inadequate to fully convey . . . the danger of PAH." *Id.* at *5.

The Court rejected both arguments. First, the Court observed that Zeltiq's "manual warned that CoolSculpting carried the risk of a 'Rare Adverse Event[ ]' of 'Paradoxical hyperplasia,' which it defined" in the manual, and it also warns that '"[s]urgical intervention may be required,' which is the exact consequence [Plaintiff] face[d]." *Id.* at *4. Second, the Court noted that no one diagnosed Plaintiff with fibroplasia, though, and the recommendation for treatment was liposuction—a treatment for fat cells like PAH. *Id.* at *4–5. And lastly, the Court found that the nurse practitioner's understanding of the PAH risk was not dispositive to adequacy under Florida's reasonableness standard, which is based on a "reasonable medical provider," not the subjective understanding of a particular provider. *Id.*; *see also id.* at *8. The Court thus concluded that "the CoolSculpting warnings accurately, clearly, and unambiguously described PAH and its consequences." *Id.* at *6.

Regarding Plaintiff's design defect claim, the Court affirmed the lower court's grant of summary judgment. The Court assessed Plaintiffs' claims under both the risk-utility and the consumer-expectations tests, given conflicting rulings in Florida and disputes by the parties over which test applied. However, the Court ultimately found that it "need not decide which of the two design defect tests applies to medical devices under Florida law" because Plaintiff's claim "fails under either test." *Id.* at *7. Under the risk utility test, the Court found that Plaintiff "fail[ed] to present any evidence of an alternative design for the CoolSculpting system that could have reduced or avoided PAH and its effect." *Id.* And regarding the consumer-expectations test, which for medical devices like CoolSculpting assesses the expectations of a learned intermediary rather than an end user, "PAH was within the realm of known (albeit rare) side effects of CoolSculpting." *Id.* at *8. Thus, Plaintiff could not show a genuine issue under either test, and the Court concluded that the district court had not erred in granting summary judgment.

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