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Court Puts “FDA-Cleared” Complaint on Ice

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The Central District of California recently dismissed, for the second time, a putative class action filed by two plaintiffs who claimed to have purchased Zeltiq Aesthetics, Inc.’s “CoolSculpting” fat-reduction treatments under the allegedly mistaken belief that the treatments had been “approved,” not just “cleared,” by the U.S. Food and Drug Administration.

The CoolSculpting “fat-freezing” procedure is the only “FDA-cleared,” non-surgical fat-reduction treatment of its kind, according to CoolSculpting’s website. It uses “controlled cooling to eliminate stubborn fat that resists all efforts through diet and exercise.” Plaintiffs alleged that the “FDA-cleared” claim was important to their decisions to purchase CoolSculpting treatments.

Plaintiffs first argued that the “FDA-cleared” claim, and a related “FDA-cleared, safe and effective” claim, were misleading partial representations that violated California law because they implied to consumers unaware of the distinction between FDA “approved” and FDA “cleared” that the device had satisfied the more rigorous FDA premarket approval application process. FDA “clearance” refers to a less rigorous Section 510(k) premarket notification clearance process, which CoolSculpting had successfully completed.

Because the plaintiffs could not explain how the factually true “FDA-cleared” claim on its own could cause reasonable consumers to believe that CoolSculpting had received FDA approval, the court found that plaintiffs had failed to carry their burden to plead facts that, if taken as true, would show a “probability that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled.”

In addition, the court noted that, according to FDA regulations, FDA clearance indicates that a device is at least as "safe and as effective as a legally marketed device," and that "special controls" applicable to Class II medical devices such as CoolSculpting provide "reasonable assurance of the safety and effectiveness" of such devices for their intended use. As a result, plaintiffs' arguments that the words "safe and effective" could be used only in connection with FDA approval and not clearance were to no avail.

Plaintiffs also argued that even if the "FDA-cleared" claims were not misleading, Zeltiq had a duty to disclose the distinctions between FDA approval and FDA clearance. The court disagreed, holding that a manufacturer's duty of disclosure to customers is limited to warranty obligations absent either an affirmative misrepresentation or a safety issue, neither of which was present here.

The court dismissed plaintiffs' "FDA-cleared" and "FDA-cleared, safe and effective" claims with prejudice. The court dismissed without prejudice plaintiffs' remaining allegations – including some about references on CoolSculpting's website to magazines and other publications that allegedly described CoolSculpting as "FDA-approved" – because the complaint did not allege with particularity that the plaintiffs were personally exposed to those representations.

Plaintiffs filed a Third Amended Complaint on July 2, 2018, in which they no longer allege that Zeltiq concealed the distinctions between FDA approval and FDA clearance, though they still maintain that Zeltiq misrepresented the true nature of CoolSculpting's FDA regulatory status. Zeltiq renewed its motion to dismiss for the third time on July 23, 2018. The case is *Carmen Otero et al. v. Zeltiq Aesthetics, Inc.*, No. 2:17-cv-03994 in the Central District of California. Watch this space for further developments.

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