[PUBLISH]

In the United States Court of Appeals

For the Eleventh Circuit

No. 21-12085

TERRANCE NELSON CATES,

Plaintiff-Appellant,

versus

ZELTIQ AESTHETICS, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Middle District of Florida
D.C. Docket No. 6:19-cv-01670-PGB-LRH

Before ROSENBAUM, BRANCH, and BRASHER, Circuit Judges.

BRASHER, Circuit Judge:

This appeal arises from a dispute about CoolSculpting, a medical device intended to minimize the appearance of fat. When Terrance Cates tried CoolSculpting, he developed a rare condition called Paradoxical Adipose Hyperplasia ("PAH"), which enlarges the targeted fat tissue. Needless to say, Cates was unhappy that CoolSculpting maximized the fat he wanted to minimize. So Cates sued Zeltiq Aesthetics, Inc., the manufacturer of the CoolSculpting system, for failure to warn and design defect under Florida law.

The district court granted Zeltiq summary judgment. On failure to warn, the district court concluded that Zeltiq's warnings about PAH were adequate as a matter of law. On design defect, the court determined that Cates failed to provide expert testimony that the risk of CoolSculpting outweighed its utility. Cates challenges both of the district court's rulings on appeal.

As to his failure to warn claim, Cates argues Zeltiq's warnings were legally inadequate because they did not demonstrate the severity of PAH. We disagree. Zeltiq warned medical providers in its user manual and training sessions about the exact condition Cates experienced: PAH is an increase of adipose tissue in the treatment area that may require surgery to correct. Accordingly, the district court properly concluded Zeltiq's warnings were adequate as a matter of law.

As to his design defect claim, Cates argues the district court should have applied the consumer expectations test, not the risk-utility test, under Florida law. We are convinced that Cates's design

defect claim fails under either test. So we need not decide which Florida-law test applies to a design defect claim about a medical device like CoolSculpting.

After reviewing the record, and with the benefit of oral argument, we cannot conclude that the district court erred in granting summary judgment to Zeltiq. Accordingly, we affirm.

I.

A.

CoolSculpting is a medical device that purports to freeze away fat without surgery. Zeltiq, the manufacturer of the CoolSculpting system, cleared its product with the FDA as a Class II prescription medical device in 2010. As a Class II medical device, CoolSculpting is sold to companies with a physician or medical director, not directly to consumers. Even so, Zeltiq advertises its product to consumers, and many consumers frequent dermatology offices, plastic surgery offices, and medical spas specifically for CoolSculpting services.

CoolSculpting works through "cryolipolysis": applying cold applicators to the body to induce "lipolysis" or the breakdown of fat cells. Medical providers apply the device to the patient's target areas, such as the lower stomach and hips, in applications or "cycles." When CoolSculpting is effective, it minimizes the appearance of fat that may not otherwise respond to diet or exercise. But in rare instances, patients develop PAH in the months following CoolSculpting. PAH produces the opposite of the intended result—

visibly enlarged tissue volume in the treatment areas. The condition gets its name from the "paradoxical" result of fat cells (adipose tissue) growing (hyperplasia) rather than shrinking. Patients who develop PAH often require liposuction or other surgery.

PAH is exactly what happened to Terrance Cates. In February 2018, Cates visited a medical spa in Orlando, Florida to receive CoolSculpting. Isis Bucci—an advanced registered nurse practitioner authorized to perform CoolSculpting under the supervision of Dr. Ayyaz Shaha—administered eight cycles of CoolSculpting to Cates. He received four cycles to his lower stomach and two on each hip. Cates returned in May 2018 for two more cycles to each hip. Then in July, Cates noticed a mass forming in his lower stomach. Cates returned to the medical spa in October, where Dr. Shaha diagnosed Cates with PAH.

After the diagnosis, additional masses formed on both of Cates's hips. Cates consulted two plastic surgeons, both of whom confirmed he had PAH. Dr. Max Polo described Cates's condition as mild "subcutaneous adiposity" or fat residing under the skin where he received CoolSculpting treatments and "bulging contour with slightly firm fat on palpitation." Similarly, Dr. Gregory Neil described Cates's PAH as three "well-defined masses" of "hyperplastic fat." Both surgeons recommended liposuction.

Cates contends Nurse Practitioner Bucci never explained to him the risk of PAH before administering his CoolSculpting treatments. In fact, Nurse Practitioner Bucci later testified in a deposition that she believed patients who did not assiduously follow post-

treatment procedures had "more chance" of developing PAH. Even so, Nurse Practitioner Bucci knew that PAH was a possible side effect of CoolSculpting that may require surgery to correct. She recounted that a coworker of hers developed PAH after a CoolSculpting procedure before Cates's CoolSculpting procedure. And according to Nurse Practitioner Bucci, that coworker required plastic surgery to correct the problem. Still, Nurse Practitioner Bucci deemed PAH "rare," given that it had occurred a handful of times in the 2,000 to 4,000 CoolSculpting procedures she had performed.

For his part, Cates signed a CoolSculpting consent form warning about the risk of PAH.[1] That form described PAH as a "rare side effect" consisting of "an enlargement of fat in the service area of varying size and shape," which "may occur in the months to year following the treatment." The consent form added that PAH is "unlikely [to] resolve on its own" but "can be removed through liposuction or related surgery."

Zeltiq also warns healthcare providers that administer CoolSculpting cycles about PAH. Under "Rare Adverse Events" in its CoolSculpting manual, Zeltiq includes, "Paradoxical hyperplasia: Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical

[1] Cates alleged that he was not given the consent form until thirty-five minutes into his first two of eight CoolSculpting procedures. Even assuming this to be true, as we must, that means he still voluntarily underwent several more CoolSculpting procedures after signing the consent form.

intervention may be required." Zeltiq also conducts training sessions that incorporate a slide on PAH. That slide describes PAH as "[l]ocal increases in subcutaneous adipose tissue" that "[p]resents as a demarcated border between treated and non treated area." The training describes the "affected tissue" as "firm compared to non treated [sic] tissue" and concedes that "[t]here is no evidence of spontaneous resolution of PAH and surgical intervention may be required."

B.

Cates sued Zeltiq, asserting five claims: (1) strict product liability based on failure to warn, (2) strict product liability based on design defect, (3) negligence, (4) negligent misrepresentation, and (5) fraudulent misrepresentation and concealment. Zeltiq sought summary judgment on all claims, which the district court granted.

First, the court dismissed Cates's failure to warn claim because Zeltiq "provided accurate, clear, and unambiguous warnings of the exact injury [Cates] experienced . . . sufficient to educate a reasonable CoolSculpting provider that the procedure carries the risk of patients developing permanent, visibly enlarge, hardened tissue in the treatment area."

Second, for Cates's design defect claim, the district court determined that Florida's "consumer expectations test" (which asks what a reasonable consumer would expect) did not govern the claim because the CoolSculpting device "is a complex medical device available to an ordinary consumer only as an incident to a medical procedure." *Cavanaugh v. Stryker Corp.*, 308 So. 3d 149, 156

(Fla. 4th DCA 2020). Instead, it concluded that the risk utility test (which asks whether the risk of a design outweighs its utility) applied. And given that Cates's experts gave no opinion about the device's risk or utility, the court dismissed the claim. Alternatively, the court concluded that, even if the consumer expectations test applied, summary judgment for Zeltiq was proper because Cates provided no expert testimony that the CoolSculpting device was defective.

Third, the court dismissed Cates's remaining three claims as "simply repurposed failure-to-warn" arguments. Consequently, the court entered a final judgment for Zeltiq.

Cates timely appealed.

II.

"We review a district judge's granting summary judgment de novo." *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1312 (11th Cir. 2014). Summary judgment is proper when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). When the plaintiff fails to provide "a sufficient showing to establish the existence of an element" of his claim, "there is no genuine dispute regarding a material fact." *Chapman*, 766 F.3d at 1312 (internal quotation omitted). We may "affirm a grant of summary judgment on any alternative ground fairly supported by the record." *Rozar v. Mullis*, 85 F.3d 556, 564 (11th Cir. 1996). In this diversity action, Florida law applies. *See Salinero v. Johnson & Johnson*, 995 F.3d 959, 964 (11th Cir. 2021).

III.

Cates argues that the district court erred in granting summary judgment on his failure to warn and design defect claims. We take up each claim in turn.

A.

A failure to warn claim under Florida law requires a plaintiff to demonstrate "(1) that the product warning was inadequate; (2) the inadequacy proximately caused [his] injury; and (3) that [he] in fact suffered an injury from using the product." *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1321 (11th Cir. 2017) (citing *Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. 1st DCA 2009)). Zeltiq argues, and the district court held, that Cates's claim fails on the first element. Cates argues there is a genuine dispute of material fact as to the adequacy of Zeltiq's PAH warnings. We agree with the district court that Zeltiq's warnings are legally adequate.

We must first address *whom* a product manufacturer must warn. In cases involving medical devices like CoolSculpting, the device manufacturer has a duty to warn "the physician who prescribes the device." *Salinero*, 995 F.3d at 964 (quoting *Buckner v. Allergan Pharms., Inc.*, 400 So. 2d 820, 823 (Fla. 5th DCA 1981) (cleaned up)). The duty is owed, not to the consumer, but to the physician or medical professional because the medical professional is a "learned intermediary." *See id.* Under Florida's learned intermediary doctrine, a learned intermediary is one who weighs "the potential benefits of a device against the dangers in deciding whether to

recommend it to meet the patient's needs." *Eghnayem*, 873 F.3d at 1321 (citing *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989)).

The question becomes, therefore, whether Zeltiq's warnings were legally adequate to warn the medical professionals who administer CoolSculpting about PAH. "While in many instances the adequacy of warnings . . . is a question of fact," the Florida Supreme Court held that this question can be resolved as "a question of law where the warning is accurate, clear, and unambiguous." *Felix*, 540 So. 2d at 105. A warning is adequate as a matter of law when it "make[s] apparent the potential harmful consequences" of the product. *Farias v. Mr. Heater, Inc.*, 684 F.3d 1231, 1233 (11th Cir. 2012) (quoting *Scheman–Gonzalez v. Saber Mfg. Co.*, 816 So. 2d 1133, 1139 (Fla. 4th DCA 2002)). Warning the learned intermediary is "somewhat easier" than warning consumers given that the warning "will be read and considered by a trained expert." *Eghnayem*, 873 F.3d at 1321–22 (quoting *Hayes v. Spartan Chem. Co.*, 622 So. 2d 1352, 1354 (Fla. 2nd DCA 1993)).

To conduct this inquiry, we put ourselves in the shoes of a "reasonable person," setting aside any individual's "subjective appreciation of the danger." *Id.* at 1233–34 (internal quotation omitted). In *Upjohn Company v. MacMurdo*, for instance, the Florida Supreme Court determined a product label for contraception was adequate as a matter of law when it put a reasonable medical professional on notice for the symptoms experienced by the plaintiff—abnormal bleeding. 562 So. 2d 680, 683 (Fla. 1990). The warning

did not require greater specificity (i.e., that bleeding may be "excessive, continuous or prolonged"), in part, because medical literature did not support such a characterization. *Id.* at 683 n.4.

With this background in mind, we ask whether Zeltiq's warnings were objectively "accurate, clear, and unambiguous," *see Felix*, 540 So. 2d at 105, to warn medical professionals about the "apparent potential harmful consequences" of PAH, *Farias*, 684 F.3d at 1234. The answer is "yes."

Zeltiq warned medical professionals about PAH and its potential consequences in both its CoolSculpting user manual and its training session materials. The manual warned that CoolSculpting carried the risk of a "Rare Adverse Event[]" of "Paradoxical hyperplasia," which it defined as "[v]isibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment." The manual also warns, "[s]urgical intervention may be required," which is the exact consequence Cates now faces. Zeltiq's training presentation similarly included a slide on PAH, describing it as "[l]ocal increases in subcutaneous adipose tissue" that "[p]resents a demarcated border between treated and non treated area" and is "firm compared to non treated [sic] tissue." Again, Zeltiq warned of the possibility that "surgical intervention may be required." Therefore, Zeltiq's warnings accurately, clearly, and unambiguously describe PAH and its consequences. *See Felix*, 540 So. 2d at 105; *Farias*, 684 F.3d at 1233.

Cates argues that the warnings about PAH were insufficient for two reasons: (1) the warnings fail to accurately reflect the

"severity of the risk," and (2) the warnings were insufficient to warn Nurse Practitioner Bucci given her alleged misunderstanding of PAH. We disagree.

First, Cates asserts that Zeltiq's warnings failed to alert medical providers about the severity of PAH because PAH is not "a mere increase in fat cells." Cates posits that PAH "is fibroplasia" or firm, scar-like tissue. But here, as in *Upjohn*, there is hardly any support in the record that PAH "is fibroplasia." *See Upjohn Co.*, 562 So. 2d at 683 n.4. In fact, none of the five medical articles Cates proffered to oppose summary judgment link CoolSculpting to fibroplasia or suggest that fibroplasia causes PAH.[2] On this record, we see

---

[2] *See* Scott A. Seaman et al., *Paradoxical Adipose Hyperplasia and Cellular Effects after Cryolipolysis: A Case Report*, 36(1) AESTHETIC SURGERY J. 6, 7 (2016) ("The precise pathogenesis of PAH"—or the manner of development—"is not well understood."); Selina M. Singh et al., *Paradoxical Adipose Hyperplasia Secondary to Cryolipolysis: An Underreported Entity?*, 47 LASERS IN SURGERY & MED. 476, 478 (2015) ("The etiology of paradoxical adipose hyperplasia is unknown."); Misbah Khan, *Complications of Cryolipolysis: Paradoxical Adipose Hyperplasia (PAH) and Beyond*, AESTHETIC SURGERY J. 6–7 (2018) ("Although the exact pathophysiology of the formation of PAH remains a mystery, a multi-factorial etiology has been speculated: hypertrophy of the preexisting adipocytes in response to cold injury, tissue hypoxia, reduction in sympathetic innervation, recruitment of preadipocytes, and/or stem cell population."); Derek Ho & Jared Jagdeo, *A Systematic Review of Paradoxical Adipose Hyperplasia (PAH) Post-Cryolipolysis*, 16(1) J. OF DRUGS IN DERM. 62, 64 (2017) ("The exact pathoetiology of PAH remains to be elucidated, but researchers have proposed several mechanisms of PAH development."); Michael E. Kelly et al., *Treatment of Paradoxical Adipose Hyperplasia following Cryolipolysis: A Single-Center Experience*, PLASTIC AND RECONSTRUCTIVE SURGERY 17e–22e (July 2018) (refraining from addressing the cause of PAH).

no legally significant distinction between a warning about PAH, which Zeltiq provided, and a warning about fibroplasia, which Zeltiq did not provide.

Moreover, after Cates's initial PAH diagnosis, he visited two plastic surgeons who did not diagnose him with fibroplasia, but instead, described Cates's masses as "subcutaneous adiposity" and "hyperplastic fat." And both recommended liposuction to remove the masses. In other words, both doctors concluded that Cates's masses were fat cells[3] and recommended liposuction to resolve the problem. Zeltiq's warnings were, thus, legally sufficient as directed to trained medical professionals to warn about the condition Cates experienced. *See Eghnayem*, 873 F.3d at 1321–22; *accord Felix*, 540 So. 2d at 105 (determining, "as to physicians, the warnings concerning the dangerous side effects" were "quite clear," even if the average consumer would not fully appreciate them).

Second, Cates argues that Zeltiq's warnings were inadequate to inform Nurse Practitioner Bucci, specifically, about the risk of PAH. In her deposition, Nurse Practitioner Bucci incorrectly attributed PAH to CoolSculpting patients' failure to adhere to post-treatment procedures. Cates relies on the principle that "a manufacturer may not be reasonable in relying on an intermediary" if it

---

[3] "Adiposity refers to the amount of adipose (fat) tissue in the body." José M. Luchsinger, M.D. M.P.H., & Deborah R. Gustafson, M.S. Ph.D., *Adiposity and Alzheimer's Disease*, Curr. Opin. Clin. Nutr. Metab. Care, Jan. 2009, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2771208/. [https://perma.cc/5USW-4CZ4].

"did not adequately convey the danger to the intermediary or take steps to ensure that the intermediary would adequately warn the end user." *Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 515 (Fla. 2015). Cates contends that Nurse Practitioner Bucci's misunderstanding about PAH is evidence that Zeltiq's warnings were inadequate to fully convey to her the danger of PAH.

But Nurse Practitioner Bucci's "subjective appreciation of the danger" is not dispositive to the adequacy of the warning. *Farias*, 684 F.3d at 1233–34 (internal quotation omitted). Whether the warning is legally adequate is based on the "reasonable person" or, here, the reasonable medical provider. *Id.* at 1233. And nothing in Zeltiq's user manual or training session materials suggests that PAH develops when patients fail to adhere to post-CoolSculpting protocols.

To be sure, whether the individual medical provider subjectively "fully understood" a warning is relevant to the element of *proximate cause*. *See Felix*, 540 So. 2d at 105. For example, if the medical professional testifies that she "fully understood the warnings" and would use the product even if the warning had been different, then the warning cannot be the proximate cause of the patient's injury. *Id.* But as to the warning's *adequacy*, our analysis under Florida law is objective.

Cates relies on the Florida Supreme Court's decision in *Aubin*, 177 So. 3d 489, but it provides Cates no assistance. The court in *Aubin* was concerned with whether the learned intermediary doctrine applied in the first place. *Id.* at 514–15. There, the

manufacturer of an asbestos product argued the learned intermediary doctrine applied when the manufacturer supplied its product through intermediary manufacturers. *Id.* at 514. Accordingly, the court zeroed in on "the critical inquiry": "whether the manufacturer was reasonable in relying on the intermediary to relay warnings to the end user." *Id.* But here, whether the learned intermediary doctrine applies is not at issue. Manufacturers of medical products, like the CoolSculpting system, are reasonable in directing warnings to medical providers because medical providers use their expertise to decide "whether to recommend [the device] to meet the patient's needs." *Eghnayem*, 873 F.3d at 1321 (citing *Felix*, 540 So. 2d at 104). Any misunderstanding by Nurse Practitioner Bucci (i.e., whether PAH results from evading post-CoolSculpting procedures) does not render it unreasonable for Zeltiq to rely on learned intermediaries.

A patient might understandably be frustrated when a learned intermediary never relays a warning that a manufacturer gave the learned intermediary. But it is not the manufacturer's job to ensure the patient gave "informed consent" to a medical procedure when a learned intermediary is involved. *Buckner*, 400 So. 2d at 824. In other words, when the warning is legally adequate to inform the learned intermediary, the learned intermediary's failure to warn the patient does "not give rise to a duty in the manufacturer." *Id.*

In any event, Zeltiq itself warned patients about PAH along with medical professionals. Zeltiq provided—and Cates signed—

consent forms that warned patients about the risk of PAH. That form described PAH as "an enlargement of fat in the service area" that is "unlikely [to] resolve on its own" and "can be removed through liposuction or related surgery." Together with Zeltiq's product manual and training presentation, the CoolSculpting warnings accurately, clearly, and unambiguously described PAH and its consequences. *See Felix*, 540 So. 2d at 105; *Farias*, 684 F.3d at 1233.

B.

We turn now to Cates's design defect claim. A design defect claim under Florida law requires "[f]irst, that the product is defective; and second, that such defect caused plaintiff's injuries." *Liggett Grp., Inc. v. Davis*, 973 So. 2d 467, 475 (Fla. 4th DCA 2007) (citing *Jennings v. BIC Corp.*, 181 F.3d 1250, 1255 (11th Cir. 1999)). Applying the risk utility test, the district court determined no genuine dispute of material fact existed for whether Zeltiq's CoolSculpting system was defective.[4] Cates argues we should reverse because the district court employed the wrong test under Florida law. Zeltiq argues, and we agree, that Cates's claim fails under any Florida law standard for assessing a design defect.

---

[4] The district court reasoned, in part, that Cates's design defect claim fails under the risk utility test for lack of supporting expert opinion. But we are satisfied that Cates did not provide evidence of defect—expert or otherwise. Accordingly, we express no opinion about whether expert testimony is necessary to establish the element of defect.

We begin with some background on design defect claims under Florida law. Two different tests determine whether a product is defective: (1) the consumer expectations test and (2) the risk utility test. The consumer expectations test, found in the Second Restatement, "considers whether a product is unreasonably dangerous because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner." *Aubin*, 177 So. 3d at 503 (citing Restatement (Second) of Torts § 402A (1965)). The risk utility test from the Third Restatement requires a plaintiff demonstrate "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . , and the omission of the alternative design renders the product not reasonably safe." *Id.* at 505 (emphasis omitted) (quoting Restatement (Third) of Torts: Products Liability § 2 (1998)). The main difference between the two tests is that the risk utility test requires that the plaintiff prove a "reasonable alternative design." *Id.*

As between the two tests, the consumer expectations test is the default under Florida law. *Id.* at 510. In *Aubin*, the Florida Supreme Court held that, "in approaching design defects claims," Florida law "adhere[s] to the consumer expectations test as set forth in the Second Restatement and reject[s] the categorical adoption of the Third Restatement and its reasonable alternative design requirement." *Id. Aubin* involved a product with asbestos used in the plaintiff's construction business. *Id.* at 495. Among the reasons *Aubin* rejected the risk utility test is that it "fails to consider the crucial link between a manufacturer establishing the reasonable

expectations of a product that in turn cause consumers to demand that product" and "places upon the plaintiff an additional burdensome element of proof, requiring the injured consumer to step into the shoes of a manufacturer and prove that a reasonable alternative design was available to the manufacturer." *Id*. at 506–07. The consumer expectations test, on the other hand, acknowledges that "a manufacturer plays a pivotal role in crafting the image of a product and establishing the consumers' expectations for that product, a portrayal which in turns motivates consumers to purchase that particular product," *id*. at 511, and places the "burden of compensating victims of unreasonably dangerous products . . . on the manufacturers, who are most able to protect against the risk of harm," *id*. at 510.

But five years later, Florida's Fourth District Court of Appeal distinguished *Aubin* and applied the risk utility test to a design defect claim involving a "complex product." *Cavanaugh*, 308 So. 3d at 155. The Fourth District reasoned, "*Aubin* did not decide whether the consumer expectations test can logically be applied to a complex medical device accessible to a consumer only through a medical professional." *Id.* The court in *Cavanaugh* then held that the consumer expectations test does not apply to design defect claims for medical devices because "medical device manufacturers generally do not market their products to 'ordinary consumers.'" *Id.* For example, the medical device in *Cavanaugh* was the "Neptune 2," a device the physician used during lung removal surgery to suction blood and surgical fluid waste. *Id*. at 151. The device was ancillary to the patient's surgery. *See id*. The court reasoned that the one of

the "rationale[s] for the consumer expectations test—that a manufacturer plays a central role in establishing the consumers' expectations for a particular product, which in turn motivates consumers to purchase the product—simply does not apply to the Neptune 2 device." *Id.* at 155.

The parties dispute whether we should follow the Florida Supreme Court's holding in *Aubin*—consumer expectations—or the Fourth District's reasoning in *Cavanaugh*—risk utility. For its part, the district court was persuaded by *Cavanaugh* and applied the risk utility test. Cates asks us to distinguish *Cavanaugh*, arguing that CoolSculpting is an unusual medical device that is marketed directly to consumers who seek medical care only to access the device. Indeed, unlike the medical device in *Cavanaugh*, CoolSculpting is not ancillary to another surgery; it is the primary service consumers seek. *See Cavanaugh*, 308 So. 3d at 155. So, even if the risk utility test were appropriate for most medical products, Cates argues that the consumer expectations test should be used to evaluate this particular device.

We need not decide which of the two design defect tests applies to medical devices under Florida law, however, because Cates's claim fails under either test. The problem is that Cates has not identified a defect in the design of CoolSculpting; he has merely pointed to a known, but rare, side effect.

If we apply the risk utility test, we agree with the district court that Cates failed to demonstrate a design defect. As discussed above, the risk utility test requires a plaintiff demonstrate "the

foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . , and the omission of the alternative design renders the product not reasonably safe." *Aubin*, 177 So. 3d at 505 (quoting Restatement (Third) of Torts: Products Liability § 2 (1998)). But Cates fails to present any evidence of an alternative design for the CoolSculpting system that could have reduced or avoided PAH and its effects. Instead, Cates's hired expert testified that CoolSculpting is "safe and effective when we understand the potential risks and benefits." That reinforces that Cates's issue with the CoolSculpting system is not the alleged design defect but the alleged failure to provide adequate warnings. If the risk utility test applies, summary judgment for Zeltiq is warranted.

If we apply the consumer expectations test, we also conclude that Cates failed to demonstrate a design defect. Under the consumer expectations test, a product is defective if "it failed to perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner." *Id.* at 503 (citing Restatement (Second) of Torts § 402A (1965)). Even so, "a manufacturer is not under a duty in strict liability to design a product which is totally incapable of injuring" consumers. *Grieco v. Daiho Sangyo, Inc.*, 344 So. 3d 11, 19 (Fla. 4th DCA 2022) (quoting *Husky Indus., Inc. v. Black*, 434 So. 988, 991 (Fla. 4th DCA 1983)). Whether a product is "unreasonable dangerous" is "based on an objective standard and not the viewpoint of any particular customer." *Liggett Grp.*, 973 So. 2d at 475 (citing *Jennings*, 181 F.3d at 1255).

The parties agree that, in a medical device case in which the consumer expectations test applies, a court must assess the expectations of the learned intermediary, not the end user. *Cavanaugh*, 308 So. 3d at 156. Assuming without deciding that we evaluate the expectations of the healthcare provider in applying this test under Florida law, Cates's design defect claim fails. Cates has produced no evidence that an objectively reasonable medical provider would believe that PAH is not a potential side effect of CoolSculpting. Instead, his own expert conceded that it is a known side effect that should be discussed with the patient before the procedure. In short, PAH was within the realm of known (albeit rare) side effects of CoolSculpting.

Cates argues that Nurse Practitioner Bucci's misconceptions about PAH are proof that the CoolSculpting system failed to meet her expectations. Not so. Nurse Practitioner Bucci's apparently erroneous notion that PAH develops in patients who fail to adhere to post-procedure care is irrelevant for two reasons. One—Nurse Practitioner Bucci understood that PAH was a possible side effect of CoolSculpting that may require surgery to correct, regardless of whether she understood its mechanism. Her deposition testimony does not support the conclusion that she was unaware of PAH or, said differently, that PAH was outside the realm of expectations of CoolSculpting. Two—Nurse Practitioner Bucci's subjective expectations about the CoolSculpting system are not definitive. We evaluate an "objective" medical provider's expectations, not Nurse Practitioner Bucci's in particular. *Liggett Grp.*, 973 So. 2d at 475.

Assuming, however, that the relevant expectations are those of the patient, we likewise conclude that there is no genuine issue of material fact that the CoolSculpting system performed as reasonably expected. "The consumer expectations test intrinsically recognizes a manufacturer's central role in crafting the image of a product and establishing the consumers' expectations for that product." *Aubin*, 177 So. 3d at 507. And we believe Cates's injury was well within the range of side effects that Zeltiq's messaging would lead a reasonable consumer to expect. In light of Zeltiq's many warnings about the possibility of PAH, including in the consent form that Cates signed, we cannot say the CoolSculpting system "failed to perform as safely as an ordinary consumer would expect." *Aubin*, 177 So. 3d at 503.

Cates contends that the CoolSculpting system failed to meet his expectation that the procedure would reduce the appearance of fat "without damage to his tissue and without the need for invasive surgery." We do not doubt that Cates did not subjectively anticipate developing PAH. He would not have engaged in CoolSculpting if he had known that he would be one of the few CoolSculpting customers who experience PAH as a side effect. But the consumer expectations test is an objective test. *Liggett Grp.*, 973 So. 2d at 475. And PAH is the kind of outcome that Zeltiq's messaging would lead an objective person to expect as a potential side effect of CoolSculpting.

In sum, under either test, Cates failed to meet his burden of demonstrating a genuine issue of material fact as to design defect.

The district court did not err in granting summary judgment for Zeltiq.

IV.

The district court is **AFFIRMED**.