APPENDIX TABLE OF CONTENTS

OPINIONS AND ORDERS

Opinion, United States Court of Appeals for the Eleventh Circuit (July 21, 2023)..... 1a

Exhibit to Eleventh Circuit Opinion: *Adiposity and Alzheimer's Disease* 22a

Order Granting Motion for Summary Judgment, United States District Court for the Middle District of Florida Orlando Division (April 19, 2021) 40a

RECONSIDERATION ORDERS

Order Denying Motion for Reconsideration, United States District Court for the Middle District of Florida Orlando Division (May 18, 2021) 58a

OPINION, UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT (JULY 21, 2023)

[PUBLISH]

73 F.4th 1342 (11th Cir. 2023)

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

TERRANCE NELSON CATES,

Plaintiff-Appellant,

v.

ZELTIQ AESTHETICS, INC.,

Defendant-Appellee.

No. 21-12085

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.

OPINION OF THE COURT

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 "hyper-plastic 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 hyper-plasia: Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical 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."

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[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.

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 involveing 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. Al-lergan 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 hyper-plasia," 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,

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[2] *See* Scott A. Seaman et al., *Paradoxical Adipose Hyperplasia and Cellular Effects after Cryolipolysis: A Case Report*, 36(1)

we see 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

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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).

[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].

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 posttreatment procedures. Cates relies on the principle that "a manufacturer may not be reasonable in relying on an intermediary" if it "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

[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

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.

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

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opinion about whether expert testimony is necessary to establish the element of defect.

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 involveing 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.

EXHIBIT TO ELEVENTH CIRCUIT OPINION:
ADIPOSITY AND ALZHEIMER'S DISEASE

ADIPOSITY AND ALZHEIMER'S DISEASE

José A. Luchsinger, MD MPH[1,2,3,4]
and Deborah R. Gustafson, MS PhD[5,6]

Abstract

Purpose of the review—Alzheimer's disease (AD) is the most common form of dementia. There are no

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known preventive or curative measures. There is increasing evidence for the role of total adiposity, usually measured clinically as body mass index (BMI), and central adiposity, measured in AD. This topic is of enormous public health importance given the global epidemic of high adiposity and its consequences.

Recent findings—Salient publications in 2007 and 2008 showed that a) central adiposity in middle age predicts dementia in old age; b) the relation between high adiposity and dementia is attenuated with older age; c) waist circumference in old age, a measure of central adiposity, may be a better predictor of dementia than BMI, d) lower BMI predicts dementia in the elderly; e) weight loss may precede dementia diagnosis by decades, which may explain seemingly paradoxical findings.

Summary—The possibility that high adiposity increases AD risk is alarming given global trends of overweight and obesity in the general population. However, prevention and manipulation of adiposity may also provide a means to prevent AD. Treatment of weight loss in AD may also be important but is beyond the score of this review.

Keywords

Alzheimer's disease; dementia; adiposity; overweight; obese; body weight

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Introduction

Alzheimer's disease (AD) is the most common form of dementia, accounting for between 70% to over 90% of all cases(1), and its prevalence is expected to quadruple by the year 2047 in the United States (2). As much as 50% of the population aged 85 years and older, the fastest growing segment of the population, may have AD (3). The risk factors for ADcan be classified as genetic and non-genetic. Three genes have been identified in familial early onset AD, Amyloid Precursor Protein (APP), Presenilin 1, and Presenilin 2 (4). These genes affect less than 5% of cases of AD, have full penetrance and expressivity, and usually affect persons in middle age (5). This review will address risk factors for late onset AD. Robust risk factors that have been identified for late onset AD include older age, lower education, and the APOE-ε4 allele(5). Importantly, APOEε4 has been found to modulate the effect of other putative risk factors (6), such as diabetes and hyperinsulinemia (7,8). It is thought that the main culprit in AD is the accumulation of amyloid ß in the brain, resulting in synapse disruption and neuronal destruction (4,9). Thus, putative treatments or prevention measures for AD must target the deposition of Aß and have the potential of preventing or delaying the onset of disease, not just symptoms (10). There are no established preventive or curative measures for AD. Thus, there is an intense search for modifiable risk factors. High adiposity is an established modifiable risk factor for several diseases(11) and has gathered interest as a risk factor for AD. This

manuscript is a brief review of the evidence linking adiposity to AD.

Definition and burden of adiposity

Adiposity refers to the amount of adipose (fat) tissue in the body (12). Some refer to adiposity as "fatness", overweight, or obesity. Adiposity is a continuum, the normal or ideal threshold of adiposity is not clear, and is affected by factors such as age, sex and ethnic group. In general, as adiposity increases it is associated with higher risk of insulin resistance, diabetes, hypertension, dyslipidemia, cardiovascular disease, degenerative joint disease, cancer, and respiratory diseases (11,13). Definitions of a high level of adiposity have been devised using simple anthropometric measures and in relationship with adverse outcomes(14). Anthropometric measures(15) such as body weight and height are used to calculate body mass index (BMI), which is defined as weight in kilograms divided by height in meters squared (kg/m2). A BMI of 25 – 29.9 kg/m2 is considered overweight, and BMI $\geq$ 30 kg/m2, obese(16). BMI is strongly correlated with total body fat tissue and is a good indirect measure of adiposity (11), although this correlation decreases in older age (17). Thus, there is controversy over whether BMI cutoffs used for adults should be used in the elderly(18).

Another commonly used measure of adiposity is waist circumference (WC). WC is meant to measure the accumulation of adipose tissue in the abdomen, the largest depot of adipose tissue in some individuals, particularly as they age. WC is thus, perhaps, a better marker of potential adverse metabolic effects of high adiposity compared to BMI (15,19). Elevated WC is

also related to a higher risk of diabetes, hypertension, dyslipidemia, and heart disease. Most studies show that it is a better predictor of adverse cardiovascular outcomes compared to BMI (20), and have therefore advocated its use as the best measure of the detrimental effects of adiposity (15). A commonly used cutoff to define elevated waist circumference is 102 cm for men and 88 cm for women (20). Other less frequently used anthropologic measures of adiposity include skinfolds and waist to hip ratio (15).

There is a concerning epidemic of high adiposity in the world (21). With the aging of the population and greater longevity, the long term consequences of these conditions are serious and burdensome. Overweight (BMI $\geq$ 25) and obesity (BMI $\geq$ 30) (22) and elevated waist circumference(23) are increasing in adults in the United States. More concerning, these trends are also observed in children and adolescents (24). Two-thirds of the United States population are overweight or obese (24).

Potential mechanisms linking adiposity to Alzheimer's disease

There are a number of potential mechanisms linking high adiposity to AD. Mechanisms summarized below include hyperinsulemia, advanced glycosylation products, adipocyte-derived hormones (adipokines and cytokines), and the influence of adiposity on vascular risk and cerebrovascular disease.

1. Hyperinsulinemia

As described previously, one of the main consequences of adiposity is insulin resistance and hyperinsulinemia (12). The role of insulin in AD is attracting

increasing attention (25). Insulin can cross the blood brain barrier from the periphery to the central nervous system and compete with A0 for insulin degrading enzyme (IDE) in the brain, including in the hippocampus (26). Insulin is also produced in the brain, and may have, alternatively, a beneficial effect on amyloid clearance (27). Peripheral hyperinsulinemia may also inhibit brain insulin production which, in turn results in impaired amyloid clearance and a higher risk of AD (27). Thus, it is possible that decreasing peripheral hyperinsulinemia and increasing brain insulin levels have the same beneficial effect on AD. A study found that rosiglitazone, a drug used in diabetes treatment which decreases insulin resistance and decreases peripheral insulin levels may also be beneficial in AD (28). Interestingly, intranasal insulin, delivered with direct access to the brain without accessing the periphery has a similar effect (27). Manipulation of blood insulin levels in humans has been demonstrated to affect cognition and levels of amyloid 0 in the cerebrospinal fluid (29,30), supporting the potential direct role of insulin in AD.

2. Advanced glycosylation end products (AGEs)

AGEs result from impaired glucose tolerance and diabetes, which often accompany or follow high adiposity and are responsible for their related end organ damage (31). AGEs can be identified immunohistochemically in senile plaques and neurofibrillary tangles, the pathologic hallmarks of AD (5). Glycation of amyloid 0 enhances its aggregation in vitro. Furthermore, receptors for AGEs have been found to be specific cell surface receptors for amyloid 0, thus potentially facilitating neuronal damage (31).

3. Adipokines and cytokines

Adipose tissue has been traditionally viewed as a passive energy-dense depot. As a dietary component, fat contains the most energy per gram than any other dietary component. Recent evidence shows that adipose tissue is active and produces a series of substances that are important in metabolism (adipokines), and inflammation (cytokines). Examples of adipokines include adiponectin (32), leptin(33), and resistin (33), and of inflammatory cytokines include Tumor Necrosis Factor-α, and Interleukin-6 (33). All are correlated with insulin resistance and hyperinsulinemia. It is unclear at this point whether adipokines and cytokines produced by adipose tissue are directly related to AD or whether they are only markers of insulin resistance and hyperinsulinemia. However, some evidence links adipokines directly to cognition. Blood leptin levels are directly correlated with adiposity, (34,35) and the CA1 nucleus of the hippocampus, which may be affected in AD, is directly affected by adipose-derived hormones such as leptin. Leptin has been shown to have numerous effects on brain development (36) and potentially on brain health in cognition and aging, affecting the function of the hypothalamus, and learning and memory processes controlled by the hippocampus. (37) In adults with a recessive mutation in the *ob* gene (homologous to *ob/ob* mice), leptin replacement is trophic for the brain, and increases gray matter tissue in the anterior cingulate gyrus, the inferior parietal lobe, and cerebellum.(38) Presence of the leptin receptor in the hippocampus, hypothalamus, amygdala, cerebellum, and brain stem indicates potentially linked regulatory mechanisms. (36, 37) Recent experimental data show that leptin and adiponectin interact directly

with hypothalamic nuclei and regulate energy expenditure and hyperphagic responses.(39,40) Leptin, may even shape the hypothalamus in the earliest stages of development and enhance cognition.(36) Direct leptin administration has been shown to improve memory processing in mice and enhance NMDA receptors.(36) However, other roles of leptin and related adipose-derived factors in the Alzheimer brain are not clear. (41-43) Fasting plasma leptin has been inversely correlated with grey matter volume in areas of the brain in which obese have reduced grey matter in comparison with lean individuals.(44)

4. Vascular risk factors and cerebrovascular disease

Cerebrovascular disease and stroke are related to a higher risk of AD (45,46). It is not clear whether cerebrovascular disease has a direct action on the amyloid cascade. Cerebrovascular disease may cause brain damage in addition to amyloid neurotoxicity that may lower the threshold for the clinical manifestation of AD (47). An autopsy study showed that large vessel cerebrovascular disease, but not small vessel disease or infarcts, were related to a higher frequency of brain neuritic plaques (48), the pathologic hallmark of AD (5). Adiposity, hyperinsulinemia, and diabetes (13), and related vascular risk factors such as hypertension and dyslipidemia are related to a higher risk of cerebrovascular disease (49). Thus, adiposity, may affect AD risk indirectly through vascular risk factors and cerebrovascular disease.

Another potential link of adiposity, vascular disease and AD is the renin-angiotensin system (RAS). The classical function of the RAS is blood pressure

regulation, but RAS may also provide a link between obesity, hypertension, and vascular syndromes, such as type 2 diabetes, and health of the brain. (50, 51) Human brain and adipose tissue express a full RAS. Adipose RAS is involved in adipocyte growth, differentiation, and metabolism.(52) The RAS is activated in response to low levels of blood pressure, when angiotensin is converted by renin to angiotensin I, which is subsequently converted to angiotensin II by ACE. Angiotensin II interacts with angiotensin receptors 1 and 2, to mediate major cardiovascular effects of the RAS, such as increasing blood pressure.(50) In the brain, angiotensin II continues conversion to angiotensin IV, which, acting through angiotensin receptor 4 (also known as insulin–regulated aminopeptidase, IRAP),(53,54) enhances learning and memory in animal models.(54)

Dementia and weight regulation

Thus far this review has covered how high adiposity may affect AD. However, the inverse relationship, that AD affects adiposity, may also occur. Brain regions and processes important for dementia are also important for the neural regulation of food intake and energy metabolism. Emotional learning, memory and complex cognition affect eating behavior and are affected in dementia. A classic example is as memory impairment is a first symptom in AD, individuals with memory impairments may forget to eat, and thus experience declines in body weight. However, 'body memory' related to food intake in general, may also influence obesity susceptibility. Numerous hypotheses relating memory, a hippocampal function, and control of energy intake, a hypothalamic function, have been brought forward. (37,55,56) One interesting

hypothesis relating establishment of body weight set points and feeding behavior to late-life body weight disturbances in AD, is related to common involvement of hippocampal subregions, for example CA1. In early AD, neuropathological lesions appear to be selectively located in medial temporal lobe structures, including the transentorhinal cortex, entorhinal cortex, and CA1 area of the hippocampal formation. (57,58) The entorhinal cortex within the temporal lobe, is an area of neuropathological, ischemic and other insults in early dementia.(59,60) Temporal atrophy, an early hallmark of dementia and cognitive decline, is a manifestation of neuronal degeneration,(61,62) and has been related to higher BMI levels 24 years before an atrophy measurement using computed tomography (CT),(63) and cross-sectionally to lower MRI measures of global brain volume in a study of women and men aged 40-66 years.(64) Higher BMI has also been shown to predict a higher rate of atrophy progression measured using serial MRI.(65) Central adiposity (high waist-to-hip ratio) has been cross-sectionally related to temporal atrophy using MRI.(66) High BMI may lead to atrophy, or alternatively, some level of atrophy or susceptibility to atrophy may be present among those with a higher BMI due to involvement of common brain structures related to energy metabolism and dementia. Having a smaller temporal lobe volume early on may contribute to dysregulatory events leading to both higher levels of BMI throughout life and/or are reflective of diminished cognitive reserve.

Review of prospective epidemiological studies linking adiposity to Alzheimer's disease

Few studies have explored the association between adiposity and AD, and several reveal conflicting findings. Elevated BMI in middle age may be associated with higher dementia risk (67,68). A recent study showed that central adiposity in middle age was related to a higher risk of dementia in older age(69). Higher BMI at ages 70, 75 and 79 years may also predict higher dementia risk (70). However, there have been reports of no association at mid-life (71) and of lower BMI related to higher AD risk(72) (73) at older ages. There are several explanations for this apparent paradox. First, age of the adiposity measure in relationship to clinical dementia onset varies across studies. Throughout life, there may exist critical periods in which risk or protective factors may have more or less impact. Second, several studies have reported weight loss preceding dementia onset (71,74), and may precede diagnosis by decades(75). Understanding the reverse causality observed for adiposity parameters in relationship to dementia onset, (76), is critical for interpretation of study findings. Third, the inclusion of different birth cohorts across studies introduces the possibility cohort effects. According to developmental origins hypotheses early life events related tobirth cohort may influence both adult adiposity and cognition throughout adult life(77). Fourth, anthropometric characteristics of populations vary around the world. If baseline BMI, whether measured at mid-life or late-life, is within a healthy range (*e.g.*, < 25 kg/m2), with low prevalence of overweight and obesity, the risky effects of high adiposity may be less likely observed. Fifth, diagnosis of dementia is not the same across

epidemiologic studies. For example, some studies use neuropsychiatric interviews, some registry data, and others, screening criteria prior to diagnosis. Related to this is that demented populations are heterogeneous and identified at different levels of severity. Given the potentially rapid changes that occur in BMI throughout the dementia process, these nuances may translate to differences in observations, and thus data interpretation. Sixth, dementia is a syndrome. Metabolic alterations occurring with dementia may vary based on expression of the syndrome. Finally, another potential explanation is ethnicity. One study in Japanese Americans showed no association of high adiposity with AD (71). A study in Northern New York City (78) found that in younger elderly (65 to 76 years of age), the association between BMI quartiles and AD resembles a U shaped-curve, while in the oldest old (> 76 years) higher BMI is related to a lower AD risk. This U-shaped association has been reported for the relation between adiposity and cardiovascular mortality(79) and underscores the difficulty in studying the effects of adiposity in older age(80). This study also found that higher waist circumference is related to higher AD risk in the younger elderly, but not in the oldest. In late life, low BMI may also be a sign of frailty due to sarcopenia (81,82) or the consequence of hyperinsulinemia (83), one of the putative mechanisms linking adiposity and AD. Table 1 describes salient publications from 2007 and 2008 relating adiposity and AD. Curiously, these publications encapsulate the paradoxes mentioned above, but also seem to explain them. The study by Whitmer et al found that central adiposity in middle age is a predictor of dementia. The study by Luchsinger et al had similar findings for persons 65 to 75 years, but not persons 76 years and older. The study by

Luchsinger et al also found that BMI in persons 65 to 75 years had a U-shape association with dementia, while there was an inverse association in persons 76 years and older. Similarly, the study by Atti et al found an inverse association between BMI and dementia in persons 75 years and older. Finally, these findings could be explained by the study by Knopman et al, which found that weight loss may precede dementia by more than 10 years.

Conclusions Implications of the evidence linking adiposity to AD

There is compelling evidence that high adiposity, particularly in middle age and in younger elderly, is related to AD. However, this evidence comes short of being considered as proof of causation until we understand the mechanisms and some of the caveats discussed in this review. It is also important to point out that AD causes weight loss. A discussion of how weight loss in AD affects outcomes is beyond the scope of this review but can be found elsewhere(84-87). If the relation between high adiposity and AD were to be causal, the public health implications are enormous. As explained before, 2/3 of the adult population of the United States are overweight or obese, and the short term trend is for this to worsen. These trends are also being observed worldwide. With increasing life expectancy we are likely to increasingly see the cognitive consequences of increased adiposity in old age. However, the other implication is that a large proportion of cases of AD could be preventable or treatable. There is existing evidence that interventions for elevated adiposity or that improve insulin sensitivity can positively affect cognition. There is a body of literature showing that aerobic exercise can improve

cognition, particularly executive-frontal abilities, in elderly people (88,89), and some of this effect could be mediated by weight loss. A small trial of diet and exercise in middle aged Japanese Americans with glucose intolerance showed improvement in memory at 6 months(90). Rosiglitazone, a potent insulin sensitizing medication with effects similar to those of exercise and weight loss, has been shown to prevent memory decline in persons with Alzheimer's disease(91). Most of these studies are short term, and the long term effects of weight loss are not clear. Furthermore, the right age group in which these interventions would be effective is not clear. The epidemiologic data seems to suggest that middle age is a critical period. Large intervention studies with lifestyle interventions(92) and drugs like metformin(93) that result in weight loss have shown that it is feasible and safe to decrease hyperinsulinemia and the risk of diabetes in middle aged populations in the long term (*e.g.* after 3 or more years). It is possible that these interventions could extend to decreasing the risk of AD in old age. Thus, it is necessary to add AD biomarkers and clinical predictors to trials that include adiposity interventions. In this regard, there are ongoing efforts to add cognitive measures to the Finnish Diabetes Prevention Study(92), and the Diabetes Prevention Program Outcomes Study(94), 2 landmark studies of interventions to lose weight and prevent type 2 diabetes. This would help clarify the mechanisms linking adiposity and AD and may reveal a strategy to prevent an important common disease for which there is no cure. For the moment, and pending the results of these studies, it seems reasonable to postulate that maintaining a healthy weight over the life course is a 'best' strategy for optimizing both body and brain

health. There are numerous clinical trials showing that weight loss lowers blood pressure, improves blood lipids and insulin resistance, and positively affects other factors that lower not only cardiovascular, but dementia risk.

Acknowledgments

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[. . .]

Table 1

Summary of salient studies published in 2007 and 2008 relating adiposity and dementia. Authors are in alphabetical order.

First author (reference)

Atti, AR (72)

Study setting and description

The Kungsholmen Project in Sweden, a prospective study of 1255 persons 75 years and older with body mass index (BMI) information at baseline followed for 3, 6, and 9 years. Incident dementia was ascertained using standard research criteria.

Findings

Persons with a BMI of 25 kg/m2 or higher had a lower dementia than persons with a BMI of 20 to 24.9 kg/m2.

First author (reference)

Knopman, DS (75)

Study setting and description

The Rochester Epidemiology Project in Rochester, MN, United States. Dementia was ascertained by a medical records linkage system. Cases of dementia were matched to controls without dementia. Weight and weight change was abstracted from medical records

Findings

There were no differences in weight between cases and controls 21 to 30 years before dementia onset. Women with dementia had lower weight than controls starting at 11 to 20 years before diagnosis.

First author (reference)

Luchsinger, JA (78)

Study setting and description

The Washington Heights Inwood Columbia Aging Project, a cohort study of persons 65 years and older followed for 5 years on average in New York City, United States; 893 had information on BMI, and 907 had information on waist circumference at baseline. Incident dementia was ascertained using standard research criteria.

Findings

Compared with persons in the first quartile of BMI, persons in the third quartile had a lower dementia. The association between BMI and dementia resembled a U shape in those younger than 76 years, while dementia risk decreased with higher BMI in those 76 years and older. The fourth quartile of waist circumference was related to a higher Alzheimer disease risk in persons younger than 76 years.

First author (reference)

Whitmer, RA. (69)

Study setting and description

A cohort study of 6,583 members of Kaiser Permanente of Northern California, United States, who had their sagittal abdominal diameter (SAD) measured. Diagnoses of dementia were from medical records an average of 36 years later

Findings

Compared with those in the lowest quintile of SAD, those in the highest had nearly a threefold increased risk of dementia. Those with high SAD (>25 cm) and normal BMI had nearly a doubling of dementia risk compared to those with low SAD (<25 cm) and normal BMI (18.5-24.9 kg/m2). Those with obesity (BMI >30 kg/m2) and high SAD over a tripling of dementia risk

ORDER GRANTING MOTION FOR SUMMARY JUDGMENT, UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA ORLANDO DIVISION (APRIL 19, 2021)

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

TERRANCE NELSON CATES,

Plaintiff,

v.

ZELTIQ AESTHETICS, INC.,

Defendant.

Case No: 6:19-cv-1670-PGB-LRH

Before: Paul G. BYRON,
United States District Judge.

This cause comes before the Court on Defendant's Motion for Summary Judgment. (Doc. 112 (the "Motion")). Plaintiff responded in opposition (Doc. 117), and Defendant filed a reply (Doc. 122). Upon consideration, the Motion is due to be granted.

I. Background

Defendant is the manufacturer of CoolSculpting, a medical device that supplies intense cooling to

targeted areas of the body to induce lipolysis (*i.e.*, the breakdown of subcutaneous fat cells). (Doc. 119, ¶ 1). In most cases, these damaged fat cells are eliminated from the body through its normal processes. (Doc. 27, ¶ 9). However, a known possible side effect of CoolSculpting treatment is Paradoxical Hyperplasia ("PH")[1]—an enlargement and hardening of tissue in the treated area. (*Id.* ¶¶ 38–39). PH requires surgical intervention because it does not resolve on its own. (*Id.* ¶ 44).

The United States Food and Drug Administration ("FDA") cleared CoolSculpting as a Class II medical device for the performance of cryolipolysis. (Doc. 119, ¶¶ 2–5). FDA regulations provide that, "[a]s a prescription device [CoolSculpting] is exempt from having adequate directions for lay use. Labeling must include, however, adequate information for practitioner use of the device [and] should include an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device." (*Id.* ¶¶ 6, 8).

Advanced registered nurse practitioner Isis Bucci ("NP Bucci") was authorized to perform CoolSculpting treatments under the general supervision of Dr. Ayyaz Shah. (Doc. 112, ¶ 10). NP Bucci performed Plaintiff's CoolSculpting treatments on February 15, 2018, and on May 18, 2018. (*Id.* ¶ 11). Plaintiff alleges

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[1] The condition is also known as Paradoxical *Adipose* Hyperplasia (abbreviated as PAH). The Amended Complaint uses—and the scientific literature appears to prefer—PAH, but the instant Motion and related filings use PH.

that he experienced PH after his CoolSculpting treatments. (Doc. 27, ¶ 97).[2]

Plaintiff initiated this action on August 27, 2019. (Doc. 1). The Amended Complaint includes five causes of action: strict products liability based on defective design (Count I), strict products liability based on failure to warn (Count II), negligence (Count III), negligent misrepresentation (Count IV), and fraudulent misrepresentation and concealment (Count V). (Doc. 27).[3] Plaintiff also seeks punitive damage. (*Id.* ¶¶ 165–168).

Defendant now moves for summary judgment on all Counts. (Doc. 112).

II. Standard of Review

A court may only "grant summary judgment if the movant shows that 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). The moving party bears the initial burden of "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials" to support its position that it is entitled to summary judgment. Fed. R. Civ. P. 56(c)(1)(A). "The burden then shifts

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[2] Plaintiff contends that he was *diagnosed* with PH, but Defendant does not concede that fact. For the purposes of this Order, the Court assumes without deciding that Plaintiff actually developed PH.

[3] The Court dismissed Counts IV and V to the extent that they rely upon misrepresentations or omissions made: (1) to the FDA, and (2) by Defendant's paid consultants. (Doc. 61).

to the non-moving party, who must go beyond the pleadings, and present affirmative evidence to show that a genuine issue of material fact exists." *Porter v. Ray*, 461 F.3d 1315, 1320 (11th Cir. 2006). "The court need consider only the cited materials" when resolving a motion for summary judgment. Fed. R. Civ. P. 56 (c)(3); *see also HRCC, LTD v. Hard Rock Café Int'l (USA), Inc.*, 703 F. App'x 814, 816–17 (11th Cir. 2017) (per curiam) (holding that a district court does not err by limiting its review to the evidence cited by the parties in their summary judgment briefs).[4]

An issue of fact is "genuine" only if "a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In determining whether a genuine dispute of material fact exists, the Court must read the evidence and draw all factual inferences therefrom in the light most favorable to the non-moving party and must resolve any reasonable doubts in the non-movant's favor. *Skop v. City of Atlanta*, 485 F.3d 1130, 1136 (11th Cir. 2007). But, "[a] mere 'scintilla' of evidence supporting the opposing party's position will not suffice; there must be enough of a showing that the jury could reasonably find for that party." *Brooks v. Cnty. Comm'n of Jefferson Cnty.*, 446 F.3d 1160, 1162 (11th Cir. 2006) (quoting *Walker v. Darby*, 911 F.2d 1573, 1577 (11th Cir. 1990)).

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[4] "Unpublished opinions are not controlling authority and are persuasive only insofar as their legal analysis warrants." *Bonilla v. Baker Concrete Constr., Inc.*, 487 F.3d 1340, 1345 (11th Cir. 2007).

III. Discussion

Defendant raises several arguments in favor of summary judgment. First, Defendant argues that Plaintiff's failure to warn claim must fail because: (1) Defendant's warnings were adequate as a matter of law, and (2) even if they were not, Plaintiff failed to produce evidence that inadequate warnings proximately caused his injuries. Second, Defendant argues that Plaintiff failed to produce evidence that the CoolSculpting device was defective. Third, Defendant argues that Plaintiff's remaining claims must fail because they are all predicated upon the inadequacy of Defendant's warnings. Finally, Defendant argues that Plaintiff's claims are preempted by federal law and that Plaintiff cannot support a claim for punitive damage.

A. Failure to Warn (Count II)

"Under Florida law, to succeed on a failure to warn claim a plaintiff must show (1) that the product warning was inadequate; (2) that the inadequacy proximately caused her injury; and (3) that she in fact suffered an injury from using a product." *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1321–23 (11th Cir. 2017) (citing *Hoffman-La Roche Inc. v. Mason*, 27 So.3d 75, 77 (Fla. 1st DCA 2009)). Defendant argues that Plaintiff cannot prove that: (1) CoolSculpting's product warnings were inadequate for prescribers, and (2) Plaintiff's prescriber would not have recommended CoolSculpting had adequate warnings been provided.

In cases involveing prescription drugs and medical devices, Florida courts have long followed the learned intermediary doctrine, under which a manufacturer's duty to warn is directed to the healthcare provider,

not the patient. *See id.*; *Buckner v. Allergan Pharms., Inc.*, 400 So.2d 820, 822 (Fla. 5th DCA 1981); *Felix v. Hoffman-LaRoche, Inc.*, 540 So.2d 102, 104 (Fla. 1989); *Beale v. Biomet, Inc.*, 492 F.Supp.2d 1360, 1367–68 (S.D. Fla. 2007).[5] CoolSculpting is a prescription medical device available only through a licensed health-care practitioner, so the learned intermediary doctrine applies.[6]

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[5] "The rationale behind the doctrine is that patients do not have access to prescription medicines without the intervention of the learned intermediary; the manufacturer therefore has no duty to warn the patient him or herself." *Beale*, 492 F.Supp.2d at 1368; *Dye v. Covidien LP*, 470 F.Supp.3d 1329, 1340 (S.D. Fla. 2020) (holding that a failure-to-warn-the-general-public allegation "improperly focuses on whether the consumer or patient was properly warned by the manufacturer" because "[u]nder Florida law, the inquiry must be physician-focused pursuant to the learned-intermediary doctrine").

[6] Plaintiff questions the "reasonableness" of Defendant's reliance on intermediaries to relay warnings to patients, citing *Aubin v. Union Carbide Corp.*, 177 So.3d 489, 515 (Fla. 2015) ("[A] manufacturer may not be able to reasonably rely on an intermediary to provide warnings if the manufacturer knows that the necessary warnings would render the product less valuable and provide an incentive to the intermediary to withhold the necessary information from the consumer."). However, *Aubin* involved an asbestos manufacturer and is therefore inapposite. As one court recently noted, "Prescription drugs and medical devices are federally regulated products that are available to patients only through a learned intermediary. This will always distinguish prescription drugs and medical devices from other consumer products." *Pringle v. Johnson & Johnson*, No. 13-81022-CIV, 2020 WL 4501834, at *4 (S.D. Fla. Jan. 30, 2020). Therefore, "In the context of prescription drugs or medical devices, the learned intermediary doctrine is still applied as a matter of law by Florida appellate courts." *Id.*; *Salinero v. Johnson & Johnson*, 400 F.Supp.3d 1334, 1347 (S.D. Fla. 2019) ("*Aubin*'s caution that the 'learned intermediary' rule is 'not a complete defense' in certain

"While in many instances the adequacy of warnings . . . is a question of fact," the Florida Supreme Court has held that "it can become a question of law where the warning is accurate, clear, and unambiguous." *Felix*, 540 So.2d at 105. "When a warning is designed to inform a 'learned intermediary,' it is somewhat easier to establish the adequacy of the warning because it will be read and considered by a trained expert." *Hayes v. Spartan Chem. Co.*, 622 So.2d 1352, 1354 (Fla. 2d DCA 1993).

"To warn adequately, the product label must make apparent the potential harmful consequences." *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)). "A drug manufacturer is 'only required to warn the prescribing physician of the possibility that the drug may cause *the injury alleged by the plaintiff*.'" *Silverstein v. Boehringer Ingelheim Pharms., Inc.*, No. 10-civ-81188, 2020 WL 6110909, at *40 (S.D. Fla. Oct 7, 2020) (quoting *Small v. Amgen, Inc.*, 134 F.Supp.3d 1358, 1367 (M.D. Fla. 2015)). The manufacturer "need not warn about the specific manner in which the injury may occur." *Id.* (citing *Pierre v. Intuitive Surgical, Inc.*, 476 F.Supp.3d 1260, 1279 (S.D. Fla. 2020)). Likewise, the manufacturer need not warn of "subsequent measures medical professionals may employ to treat [such] injuries." *Dye*, 470 F.Supp.3d at 1341.

Before addressing the content of Defendant's warnings, the Court must begin by discussing what we know about PH—and what we do not.[7] "Macroscopically,

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cases has not been applied to medical device cases in Florida.").

[7] The following discussion draws from the five scientific articles

PAH is characterized by the formation of a large, painless, firm, partially mobile mass that develops at the [CoolSculpting] treatment site where the applicators of the cryolipolysis machine were applied to the body." (Doc. 117-25, p. 3). On a microscopic level, the affected area appears to have an "increased number of adipocytes [*i.e.*, fat cells], fibrosis [*i.e.*, thickening/ scarring of connective tissue] and scar tissue in the treated areas." (Doc. 117-23, p. 4).

PH generally appears three to six months following CoolSculpting treatments. (*Id.*). Beyond that, the underlying mechanism for the development of PH is unknown. Although several explanations have been speculated,[8] "the exact pathophysiology of the formation of PAH remains a mystery." (Doc. 117-25, pp. 3–4).[9] Every scientific article cited by Plaintiff characterizes PH as "rare." (Docs. 117-23, 117-24, 117-25, 117-26, 117-31).

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cited by Plaintiff. (Doc. 117, p. 9 n.31) (citing Docs. 117-23, 117-24, 117-25, 117-26, 117-31).

[8] "[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." (Doc. 117-25, pp. 3–4). PH may also be "due to fibrosis from the less vascularized, more hypoxic affected adipose tissue." (Doc. 117-24, p. 8).

[9] *See also* (Doc. 117-23, p. 4) ("The etiology of paradoxical adipose hyperplasia is unknown."); (Doc. 117-24, p. 3) ("The precise pathogenesis of PAH is not well understood, with only a few studies examining this phenomenon."); (Doc. 117-26, p. 4) ("The exact pathoetiology of PAH remains to be elucidated, but researchers have proposed several mechanisms for PAH development.").

PH does not resolve on its own, so removal of the affected tissue requires surgical intervention.[10] "Treatment must be performed only when the [affected] tissues have softened, usually between 6 and 9 months after cryolipolysis [rather than] during the initial firm inflammatory phase." (Doc. 117-23, p. 5). "Power-assisted liposuction is the preferred method of treatment, but in some cases, abdominoplasty [*i.e.*, a tummy-tuck] may be necessary." (*Id.* at p. 7). "Most patients will need only one liposuction." (*Id.* at p. 5).

Having laid this foundation, the Court turns to Defendant's warnings. CoolSculpting providers receive a User Manual, which contains a section discussing common and rare adverse side effects. (Doc. 112-1).[11] Under the "Rare Adverse Events" subheading, PH is listed first. (*Id.* at p. 6). The condition is described as follows: "Paradoxical hyperplasia: Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical intervention may be required." (*Id.*). The User Manual also provides a list of references, which includes four published papers discussing the risk and symptoms of PH in greater detail. (*Id.* at p. 14).

Defendant also delivered in-person training to Plaintiff's CoolSculpting providers. (Doc. 112-6, p. 29).

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[10] The Court notes that PH does not appear to *require* surgical intervention—at least, not in the same way that (for example) appendicitis does. Many patients decide not to undergo surgery to correct their PH. (*See* Doc. 117-32, p. 4).

[11] NP Bucci—Plaintiff's CoolSculpting provider—confirmed that the User Manual was kept on-site and that she reviewed the User Manual prior to Plaintiff's treatments. (Doc. 112-6, pp. 34–35).

This training included a PowerPoint presentation, which featured several slides on "Clinical Considerations for Treatment." (Doc. 112-8, pp. 18–20). A slide devoted exclusively to PH discussed the condition using the following bullet points:

> [1] Local increase in subcutaneous adipose tissue; [2] Generally develops four to five months post treatment but can be seen as early [as] two months after; [3] Presents as a demarcated border between treated and non-treated area; [4] The affected tissue is firm compared to non treated tissue; [and 5] There is no evidence of spontaneous resolution of PAH and surgical intervention may be required.

(*Id.* at p. 20). The slide also contains a picture of a PH patient's midsection. (*Id.*). Finally, the slide references a *JAMA Dermatology* article entitled "Paradoxical Adipose Hyperplasia After Cryolipolysis." (*Id.*) (citing Doc. 117-20).

Defendant even supplies CoolSculpting providers with sample patient consent forms. (Doc. 112-10). The form identifies PH as a "potential side effect[]/ risk[]," describing the condition as follows:

> A small number of patients have experienced gradual development of a firmer enlargement, of varying size and shape, of the treatment area, known as "paradoxical hyperplasia", in the months following the treatment. If such paradoxical hyperplasia occurs, it will be distinguishable from temporary swelling and will probably not resolve on its own. The enlargement/lump can be removed by means

> of a surgical procedure such as liposuction.

(*Id.* at p. 2). Plaintiff's CoolSculpting provider used strikingly similar language in its "Informed Consent and Authorization" form:

> Paradoxical hyperplasia, or an enlargement of fat in the service area of varying size and shape, may occur in the months to year following the treatment. If paradoxical hyperplasia occurs, it is unlikely that it will resolve on its own. The enlargement can be removed through liposuction or related surgery.

(Doc. 112-7, p. 1). Plaintiff acknowledged and signed this form before receiving treatment. (*Id.*).

Altogether, the undisputed evidence shows that Defendant repeatedly warned CoolSculpting providers about the risk of PH. These communications described the symptoms of PH, explained that the condition requires surgery to correct, and directed intermediaries to additional resources. Even viewed in the light most favorable to Plaintiff, the Court finds that Defendant provided accurate, clear, and unambiguous warnings of the exact injury Plaintiff experienced.[12] These warn-

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[12] *Cf. Silverstein*, 2020 WL 6110909, at *40 ("[The plaintiff's] injury was a serious gastrointestinal bleed. Even viewed in the light most favorable to [the plaintiff], the [drug's] label contains accurate, clear, and unambiguous warnings to the treating physician that [the drug] can cause fatal gastrointestinal bleeding."); *Upjohn v. MacMurdo*, 562 So.2d 680, 683 (Fla. 1990) ("The fact remains that the insert warned of the possibility of bleeding outside of the menstrual period. It would be unreasonable to hold [the defendant] liable for not characterizing the bleeding as

ings were sufficient to educate a reasonable CoolSculpting provider that the procedure carries the risk of patients developing permanent, visibly enlarged, hardened tissue in the treatment area. Therefore, these warnings enabled providers to weigh the risks and benefits before making a treatment recommendation.

Plaintiff argues that Defendant "was highly motivated to downplay the severity, permanency, and frequency of the adverse effect." (Doc. 117, p. 14). He argues that Defendant knew—and, therefore, should have warned—that PH "was a serious and permanent tissue disease called *fibroplasia* that required multiple types of surgeries to correct and in some cases, it could not be corrected with surgery." (*Id.*). Not only does this contention lack evidentiary support, it is directly contradicted by the scientific articles cited *by Plaintiff*. As discussed, the articles offer hypotheses on the pathophysiology of PH, but make clear that such theories are speculative. Likewise, the articles indicate that most PH cases require a *single* corrective surgery, and there is no evidence that some cases of PH are irreversible. (Doc. 117-32, p. 5). Finally, every authority cited by Plaintiff describes the frequency of PH as "rare," which is the same term used by Defendant's warnings.[13] Accordingly, there

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excessive, continuous, or prolonged.").

[13] Plaintiff also offers the puzzling argument that, "Contrary to what [Defendant] knew at the time, in March 2014, its consultants published a scholarly article announcing the condition to the medical community that *misnamed* the condition as 'Paradoxical *Adipose* Hyperplasia[', *misstated* the incidence rate, and *misrepresented* to the readers that PH is an 'increase in adipose tissue.'" (Doc. 117, p. 15) (citing Doc. 117-20). First,

was nothing inaccurate or misleading about Defendant's warning that PH was a rare side effect causing visibly enlarged tissue volume that does not go away on its own and may require surgical intervention.

Accordingly, Defendant's warnings to CoolSculpting providers (*i.e.*, learned intermediaries) were adequate as a matter of law. Defendant is therefore entitled to summary judgment on Count II.[14]

B. Design Defect

"Under Florida law, a plaintiff suing on a products liability claim must prove, through expert testimony, that a product defect existed and that such defect caused injury." *Salinero*, 400 F.Supp.3d at 1343. Defendant argues that Count I must fail because neither of Plaintiff's experts offered any opinion that the CoolSculpting system's design was defective. (Doc. 112, p. 17).

Florida courts recognize the "consumer expectations test" and the "risk utility test" as "alternative

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Plaintiff offers no legal support for attributing this article to Defendant. Second, the article explicitly acknowledges that, in addition to "a local increase in subcutaneous adipose tissue," PH causes "thickened fibrous septae," and such "[s]eptal thickening may be a result of reactive fibrosis owing to damaged adipocytes." (Doc. 117-20, pp. 3–4). Third, subsequent articles confirm that AH tissue shows an "increased number of adipocytes." (Doc. 117-23, p. 4). Finally, each article cited by Plaintiff uses the term Paradoxical Adipose Hyperplasia—and Plaintiff himself even uses this term. Therefore, the Court rejects Plaintiff's argument that Defendant (via its consultants) bamboozled the scientific community into adopting a misleading name for the condition.

[14] Because the warnings were adequate, the Court need not address causation.

definitions of design defect." *Aubin*, 177 So.3d at 512. As the standard jury instructions approved by the Florida Supreme Court explain:

> A product is defective because of a design defect if it is in a condition unreasonably dangerous to [the user] [a person in the vicinity of the product] and the product is expected to and does reach the user without substantial change affecting that condition.
>
> A product is unreasonably dangerous because of its design if [the product fails to perform as safely as an ordinary consumer would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer] [or] [the risk of danger in the design outweighs the benefits].

In re Standard Jury Instructions in Civil Cases–Report No. 19-03, 290 So.3d 840 (Fla. 2020).

However, "the consumer expectations test cannot be logically applied . . . where the product in question 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) (distinguishing *Aubin*).[15] Accordingly,

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[15] *Cavanaugh* emphasized that *Aubin* "did not express disagreement with or disapproval of cases recognizing that some products may be too complex for a logical application of the consumer expectations test." *Id.*; *see also Tillman v. C.R. Bard, Inc.*, 96 F.Supp.3d 1307, 1339 (M.D. Fla. 2015) ("Because this case pertains to a complex medical device, accessible to the consumer only through a physician, the Court finds that the consumer-expectation test is not applicable here."); *In re Fosamax Prods. Liab. Litig.*, 742 F.Supp.2d 460, 470 n.4 (S.D.N.Y. 2010) (applying Florida law and concluding that "prescription pharmaceuticals

Plaintiff's experts must demonstrate that CoolSculpting was unreasonably dangerous under the risk utility test.

They offer no such opinion. In fact, one of Plaintiff's experts testified that she had offered CoolSculpting to a patient the day before her deposition and actually performed CoolSculpting on a patient earlier that week. (Doc. 92-2, p. 199). She further testified that she "would not offer CoolSculpting if [she] didn't believe it was safe and effective for the patients [she] [chose] to offer it for." (*Id.*). Therefore, Plaintiff fails to present evidence that the risk of danger in CoolSculpting's design outweighs its benefits.

Even if the consumer expectations test did apply in this case, Plaintiff still fails to meet his burden. "Regardless of whether the Court applies the consumer expectations test or risk utility theory, a design defect claim must be proven by expert testimony." *Crawford v. ITW Food Equip. Grp., LLC*, No. 3:16-cv-1421, 2018 WL 3599212, at *10 (M.D. Fla. Apr. 19, 2018); *see also Cooper v. Old Williamsburg Candle Corp.*, 653 F.Supp.2d 1220, 1225 (M.D. Fla. 2009) ("[The plaintiff's] failure to offer expert evidence forecloses any claim based on design defect."). Here, neither expert offers *any* opinion on the design of the CoolSculpting device, let alone an opinion that the design was defective. (Docs. 91-1; 91-2; 92-1; 92-2).

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are too complex for the straight-forward application of the consumer expectation test"); *Rydzewski v. DePuy Orthopaedics, Inc.*, 11-80007-CIV, 2012 WL 7997961, at *3 (S.D. Fla. Aug. 14, 2012) (concluding that consumer expectation theory did not apply to a hip implant device, which was "closer to prescription drugs than to seatbelts and other products routinely operated by consumers").

Instead, Plaintiff appears to repackage his failure to warn claim as a design defect claim, arguing that Defendant's inadequate warnings prevented the CoolSculpting device from performing as safely as an ordinary consumer would expect. The closest Plaintiff's expert gets to an opinion on this point is to testify that "[CoolSculpting] is safe and effective when we [*i.e.*, providers] understand the potential risks and benefits, as well as inform our patients." (Doc. 92-2, p. 199). As discussed above, Defendant adequately warned Plaintiff's providers about the risks of PH. And, as demonstrated by Plaintiff's signed "Informed Consent and Authorization" form, he too was made aware of those risks. (Doc. 112-7, p. 1). Therefore, it is unreasonable to suggest that Plaintiff's injury was unexpected.

Thus, Defendant is entitled to summary judgment on Count I.

C. Negligence, Negligent Misrepresentation, and Fraud

Defendant next argues that, "No matter how he dresses them up, Plaintiff's counts of general negligence, negligent misrepresentation, and fraud are simply repurposed failure-to-warn claims." (Doc. 112). The Court agrees. Each of these claims are premised upon the allegation that Defendant failed to provide an adequate warning.[16] Because the Court finds that

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[16] The Court notes that the learned intermediary doctrine also applies to each of these claims. *See Beale*, 492 F.Supp.2d at 1373 (quoting *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F.Supp. 700, 709 (E.D. Tex. 1997) ("The gravamen of all of [the plaintiffs'] causes of action . . . is that [the defendant] failed to adequately warn of or disclose the severity of Norplant's side

Defendant's warnings were adequate as a matter of law, any claims derived from those warnings must fail. *See Nunez v. Coloplast Corp.*, 461 F.Supp.3d 1260, 1268 (S.D. Fla. 2020) (finding medical device warnings adequate as a matter of law and dismissing fraud claims as "mere repacking" of the failure to warn claim). Thus, Defendant is entitled to summary judgment on Counts III–V.

D. Preemption and Punitive Damages

Finally, Defendant argues that Plaintiff's claims are preempted by federal law and that Plaintiff cannot support a claim for punitive damage. The Court need not address the preemption question because Defendant is already entitled to summary judgment on alternative grounds. *Cf. Williamson v. Brevard Cnty.*, 928 F.3d 1296, 1317 (11th Cir. 2019) ("A fundamental and longstanding principle of judicial restraint requires that courts avoid reaching constitutional questions in advance of the necessity of deciding them."). Likewise, summary judgment in Defendant's favor obviously precludes Plaintiff's recovery of punitive damage.

IV. Conclusion

For the aforementioned reasons, Defendant's Motion for Summary Judgment (Doc. 112) is GRANTED. The Clerk of Court is DIRECTED to enter judgment in favor of Defendant, and thereafter, to close the case.

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effects. . . . If the [learned intermediary doctrine] could be avoided by casting what is essentially a failure to warn claim under a different cause of action . . . then the doctrine would be rendered meaningless.")). Defendant does not dispute this conclusion. (Doc. 117, p. 25).

DONE AND ORDERED in Orlando, Florida on April 19, 2021.

/s/ Paul G. Byron
United States District Judge

Copies furnished to:

Counsel of Record
Unrepresented Parties

ORDER DENYING MOTION FOR RECONSIDERATION, UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA ORLANDO DIVISION (MAY 18, 2021)

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

TERRANCE NELSON CATES,

Plaintiff,

v.

ZELTIQ AESTHETICS, INC.,

Defendant.

Case No: 6:19-cv-1670-PGB-LRH

Before: Paul G. BYRON,
United States District Judge.

This cause comes before the Court on Defendant's Motion for Reconsideration. (Doc. 136 (the "Motion")). Upon consideration, the Motion is due to be denied.

I. Background

Plaintiff initiated this action on August 27, 2019. (Doc. 1). The Amended Complaint included five causes of action: strict products liability based on defective

design (Count I), strict products liability based on failure to warn (Count II), negligence (Count III), negligent misrepresentation (Count IV), and fraudulent misrepresentation and concealment (Count V). (Doc. 27).[1] Plaintiff also sought punitive damage. (*Id.* ¶¶ 165–168). Defendant moved for summary judgment on all Counts. (Doc. 112). The Court granted the Motion. (Doc. 132). Plaintiff now asks the Court to reconsider its decision. (Doc. 136).

II. Discussion

Reconsideration is an extraordinary remedy which will only be granted upon a showing of one of the following: (1) an intervening change in law, (2) the discovery of new evidence which was not available at the time the Court rendered its decision, or (3) the need to correct clear error or manifest injustice. *Fla. Coll. of Osteopathic Med., Inc. v. Dean Witter Reynolds, Inc.*, 12 F.Supp.2d 1306, 1308 (M.D. Fla. 1998). "A motion for reconsideration cannot be used to relitigate old matters, raise argument or present evidence that could have been raised prior to the entry of judgment." *Wilchombe v. TeeVee Toons, Inc.*, 555 F.3d 949, 957 (11th Cir. 2009) (internal quotation marks omitted). It is wholly inappropriate in a motion for reconsideration to relitigate the merits of the case or to "vent dissatisfaction with the Court's reasoning." *Madura v. BAC Home Loans Servicing L.P.*, No. 8:11-cv-2511, 2013 WL 4055851, at *2 (M.D. Fla. Aug. 12, 2013) (citation omitted). Instead, the moving party must set

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[1] The Court dismissed Counts IV and V to the extent that they relied upon misrepresentations or omissions made: (1) to the FDA, and (2) by Defendant's paid consultants. (Doc. 61).

forth "strongly convincing" reasons for the Court to change its prior decision. *Id.* at *1.

Plaintiff does not contend that there has been an intervening change in controlling law[2] or the discovery of new evidence that would warrant the Court reconsidering its Order granting summary judgment in favor of Defendant. Moreover, although Plaintiff couches his Motion in terms of correcting clear error and manifest injustice, Plaintiff does nothing more than re-argue the positions he previously set forth, raise new arguments that are untimely and unpersuasive, and vent his dissatisfaction with the Court's ruling.

Plaintiff also purports to cite evidence "overlooked" by the Court. To be sure, the Court did not discuss each and every piece of evidence cited by the parties. However, none of the evidence emphasized by Plaintiff in the instant Motion change the Court's ultimate conclusion: "[T]here was nothing inaccurate or misleading about Defendant's warning that PH was a rare side effect causing visibly enlarged tissue volume that does not go away on its own and may require surgical intervention." (Doc. 132, p. 11–12).

Because Plaintiff asserts no meritorious reason for the extraordinary remedy of reconsideration, the Motion will be denied.

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[2] Plaintiff does cite to a recent order from a Florida trial court declining to find that Defendant's warnings were adequate as a matter of law. (Doc. 136-12). This decision, which had no meaningful analysis, is not a change in *controlling* law.

III. Conclusion

For these reasons, it is ORDERED AND ADJUDGED that Plaintiff's Motion for Reconsideration (Doc. 44) is DENIED.

DONE AND ORDERED in Orlando, Florida on May 18, 2021.

/s/ Paul G. Byron
United States District Judge

Copies furnished to:

Counsel of Record