Vesoulis v. ReShape Lifesciences, Inc. Doc. 116

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

PAUL VESOULIS	CIVIL ACTION
v.	NO. 19-1795
RESHAPE LIFESCIENCES, INC.	SECTION "F"

ORDER AND REASONS

Before the Court are two motions for summary judgment. In one, defendant ReShape Lifesciences, Inc. seeks dismissal of all of the plaintiff's claims against them. In another, ReShape's co-defendants, Dr. Thomas Lavin and Surgical Specialists of Louisiana, LLC, seek dismissal of the plaintiff's informed consent claims against *them*. For the reasons that follow, both motions are GRANTED.

Background

This case pits Ohio dentist Dr. Paul Vesoulis against a Louisiana bariatric surgeon (Dr. Thomas Lavin), his employer (Surgical Specialists of Louisiana, LLC, or "SSL"), and the maker of a weight-loss device[1] that perforated Vesoulis's esophagus when

[1] The device at issue is alternatively styled in the record as an "Integrated Dual Balloon" and a "Duo Gastric Balloon." Whatever its official name though, there is no dispute over its essential characteristics and function – as ReShape describes its own product, the device is little more than a "balloon" that "is

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it was removed from his stomach (ReShape Lifesciences, Inc.). Vesoulis sued the defendants in Louisiana state court on January 10, 2019. On February 27, 2019, the defendants removed the action to this Court. In the controlling complaint,[2] Vesoulis advances separate, but related, theories for recovery against both sets of defendants.

Vesoulis's claims against ReShape sound in product liability and failure to warn. Specifically, Vesoulis alleges that ReShape "is liable based solely upon [its] failure to comply with [the FDA's premarket approval (PMA)] Order and applicable FDA regulations, and thereby, is also liable under the Louisiana Products Liability Act's parallel provisions regarding failure to warn and . . . post-sale duty to warn." See Second Am. Compl., ¶ 7 (citations omitted). In particular, he asserts that ReShape is liable for failing to comply with a variety of FDA regulations regarding labeling and warnings, "communicating instances of death

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inserted into the stomach and removed several months later," and "designed to occupy space in the stomach [to] produce a sensation of satiety [and] promote weight loss." See ReShape Mot. at 3.

[2] Vesoulis's second amended complaint in this Court – with all applicable incorporations by reference – controls for present purposes. The Court accordingly disregards Vesoulis's state-court petition because he chose not to reference it in his subsequent federal-court pleadings. See, e.g., Eason v. Holt, 73 F.3d 600, 603 (5th Cir. 1996) (observing "the well-settled law of this circuit" that an amended complaint supersedes an original complaint where a plaintiff does not specifically incorporate allegations in the original complaint by reference).

or serious injury," "reporting of instances of death or serious injury through the required filing of reports with the FDA," and "communicat[ing] instances of death or serious incidents to" Dr. Lavin and SSL. Id. ¶ 8. In the briefs Vesoulis filed in opposition to the current motions – if not in his complaint – Vesoulis focuses on ReShape's failure to "advise" Vesoulis or Dr. Lavin of two deaths of which it "*knew* [to have] occurred *before* [Vesoulis's] balloons were inserted but *after* PMA approval when the FDA specifically [required] in the PMA Order [that ReShape] update labeling and be 'truthful and not misleading.'" See Opp'n to ReShape Mot. at 6. In essence, Vesoulis claims that he would not have elected to have a ReShape weight-loss balloon implanted in his stomach if he had been appropriately warned that balloon-related complications had killed two prior patients. ReShape seeks dismissal of all such claims in its present motion for summary judgment.

Vesoulis also brings a variety of medical malpractice claims against Dr. Lavin and SSL. Specifically, he asserts that his injuries "were [] caused by the medical negligence" of Dr. Lavin and SSL in failing to:

(1) "render proper and professional health care";
(2) "exercise the degree of skill and care employed under similar circumstances by physicians and health care professionals in good standing" in Louisiana and within Dr. Lavin's specialty;
(3) "properly diagnose [Vesoulis's] condition and promptly treat [the] same";

(4) remove the balloon at issue from Vesoulis's stomach without negligently tearing his esophagus; and
(5) "use reasonable care and diligence when rendering medical services to [Vesoulis], including [negligently] failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent pursuant to La. R.S. 40:1299.40."

See Second Am. Compl., ¶ 9(a).[3]

I.

Federal Rule of Civil Procedure 56 provides that summary judgment is appropriate where the record reveals no genuine dispute as to any material fact such that the moving party is entitled to judgment as a matter of law. No genuine dispute of fact exists where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). A genuine dispute of fact exists only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

The Supreme Court has emphasized that the mere assertion of a factual dispute does not defeat an otherwise properly supported motion. See id. Therefore, where contradictory "evidence is merely colorable, or is not significantly probative," summary

[3] This paragraph of the controlling complaint concludes with a catch-all allegation of "other acts of neglect, fault, or omission or commission which may become apparent through the discovery process." See Second Am. Compl., ¶ 9(a).

judgment remains appropriate. Id. at 249–50 (citation omitted). Likewise, summary judgment is appropriate where the party opposing the motion fails to establish an essential element of its case. See Celotex Corp. v. Catrett, 477 U.S. 317, 322–23 (1986). In this regard, the nonmoving party must do more than simply deny the allegations raised by the moving party. See Donaghey v. Ocean Drilling & Expl. Co., 974 F.2d 646, 649 (5th Cir. 1992). Instead, it must come forward with competent evidence, such as affidavits or depositions, to buttress its competing claim. Id. Hearsay evidence and unsworn documents that cannot be presented in a form that would be admissible at trial do not qualify as competent opposing evidence. FED. R. CIV. P. 56(c)(2); Martin v. John W. Stone Oil Distrib., Inc., 819 F.2d 547, 549 (5th Cir. 1987) (per curiam).

Finally, in evaluating a summary judgment motion, the Court must read the facts in the light most favorable to the nonmoving party. Anderson, 477 U.S. at 255.

II.

With the foregoing legal standards in view, the Court evaluates each present motion in turn.

A. Dr. Lavin and SSL's Motion for Summary Judgment

In a comparatively narrow motion, Dr. Lavin and SSL urge the Court to dismiss Vesoulis's informed consent claims. Their argument is straightforward. In essence, they contend that

Vesoulis's informed consent claim falls flat factually for three related reasons. First, because "Dr. Lavin [could not] disclose risks of which he [was] unaware." See Lavin & SSL Mot. at 7. Second, because every consent form that Vesoulis signed did in fact advise him of the very risks he claims he would not have accepted with regard to the elective procedure at issue if he had been appropriately warned – namely, death and/or esophageal perforation.[4] See id. at 8. And third, because any specific warning about the one gastric perforation that Dr. Lavin *did* learn about during his course of dealing with Vesoulis could not possibly have influenced Vesoulis's decision to undergo the balloon-removal operation that ultimately injured him. See id.

The record reveals that Dr. Lavin and SSL are correct in all such regards. For starters, it is undisputed that the "adverse events" Vesoulis complains of not being warned about were known to ReShape but "*not* made known to Dr. Lavin, SSL," or Vesoulis. See Pl.'s Resp. to Statement of Uncontested Fact No. 8, at 8 (emphasis added). Thus, to the extent that Vesoulis seeks damages for not being warned of adverse events, his assertion fails on this record.

[4] Vesoulis's position on this point is admittedly more nuanced. With the record clearly revealing that he *was* warned of a possibility of death and esophageal perforation in consent forms that he surely has above-average experience in reviewing as a doctor himself, he claims that a specific warning about two patients that *did in fact* die from the balloon procedure at issue would have made the risk of death more tangible and altered his mental calculation with regard to the procedure.

Obviously, one cannot warn of adverse events without knowledge of such events. And the record is clear; Dr. Lavin and SSL had no such knowledge.

Moreover, it is undeniable that an "Endoscopic Balloon Procedure Consent Form" bearing Vesoulis's signature *did* warn of risks of "Death (very rare)" and "[harm to] upper gastrointestinal tract or intra-abdominal organs including perforation (tearing)." See Lavin & SSL Mot., Ex. C at 1. In light of this clear warning, Vesoulis's central argument that the ReShape balloon Instructions for Use and/or Dr. Lavin's warning to Vesoulis failed to "warn that the ReShape device was associated with two deaths . . . prior to [Vesoulis's] implant" is unavailing on this record, particularly as it relates to Vesoulis's informed consent claim against Dr. Lavin and SSL. See Pl.'s Resp. to Statement of Uncontested Fact No. 8, at 8–9. Even clearer on the record is that Vesoulis signed a form that warned of the injury he *did* suffer.

Applying these undisputed facts to Louisiana's well-settled law on informed consent, it is clear that Vesoulis's informed consent claim against Dr. Lavin and SSL fails as a matter of law. To prevail on such a claim, Vesoulis must show that:

> (1) the adverse results of [his] surgery were known, significant, and material risks which should have been disclosed to [him] by [Dr. Lavin]; (2) those risks were not disclosed by [Dr. Lavin]; (3) [Vesoulis] was unaware

> of those risks; and (4) a reasonable person would have refused the surgery because of the risks.

Hondroulis v. Schuhmacher, 553 So. 2d 398, 404 (La. 1988) (footnote omitted).

Vesoulis's claim on this record fails to make a prima facie case under this standard. Vesoulis's arguments to the contrary are unavailing and shroud the fundamental reality at the heart of the matter: namely, that Vesoulis suffered an esophageal perforation that was a known and warned risk of a procedure to which he consented in writing. See Celotex, 477 U.S. at 322.

B. ReShape's Motion for Summary Judgment

That leaves ReShape's motion for summary judgment. Before evaluating Vesoulis's ability to state a plausible claim for relief on the developed record, the Court briefly addresses ReShape's initial argument that Vesoulis's claims are expressly preempted under the Supremacy Clause. See U.S. CONST. art. VI.

1. Express Preemption

ReShape devotes the bulk of its motion to arguing that Vesoulis's claims – all of which are based on Louisiana law – are expressly preempted by the Medical Device Amendments Act of 1976. However, while the parties' extensive briefing on the question of express preemption was welcome and helpful, the Court need not address the issue because Vesoulis's claims fail for other reasons anyway.

2. Liability Under Louisiana Law and Implied Preemption

a. Standard

Rule 56 "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a sufficient showing to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex, 477 U.S. at 322. Urged at this stage in the proceedings, the state-law portion of ReShape's motion for summary judgment reads and functions like a Rule 12(b)(6) motion to dismiss for failure to state a claim upon which relief can be granted. In essence, ReShape argues that the undisputed facts in the record, even when read in the light most favorable to Vesoulis, do not establish that Vesoulis has a plausible claim for relief against ReShape. If ReShape is correct, then the Court must indeed grant summary judgment in its favor and dismiss Vesoulis's claims as legally baseless. See id. The Court thus proceeds to evaluate Vesoulis's ability to state a viable claim on the developed facts in the record.

As the Court explains below, Vesoulis's claims against ReShape fare no better than his informed consent claim against Dr. Lavin and SSL.

b. Analysis

Because Vesoulis lacks an express or implied right of action under the federal law he claims that ReShape has violated,[5] he premises his claims against ReShape on asserted violations of the Louisiana Products Liability Act's (LPLA) provisions on failure to warn. In particular, Vesoulis alleges that ReShape's actions violated subsections (A) and (C) of § 2800.57 of the LPLA.[6] Together with its surrounding provisions, § 2800.57 supplies a state-law cause of action to plaintiffs who are injured by a product that is "[u]nreasonably dangerous because of inadequate warning" by its manufacturer. In full, that section of the statute provides as follows:

> A. A product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use

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[5] See Bausch v. Stryker Corp., 630 F.3d 546, 557–58 (7th Cir. 2010) (noting, under the general rule that federal courts are loath to imply rights of action that Congress could have just as easily expressly provided, that similarly situated "plaintiffs . . . did not have an implied right of action under federal law"). The federal courts of appeals have done yeoman's work in elucidating this challenging area of the law. For a helpful explanation of the "narrow gap" that a plaintiff's state-law medical-products liability claim must thread to avoid federal preemption, see *In re* Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010).

[6] In the pertinent paragraph of the controlling complaint, Vesoulis actually references *§ 9:2800(C)*, but because that provision is not a part of the LPLA and appears to have no relevance in this case, the Court assumes that this was a typographical error (i.e., omitting the "57" in "§ 9:2800.57(C)").

> reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.
>
> **B. A manufacturer is *not* required to provide an adequate warning about his product when:**
>
> > **(1) The product is not dangerous to an extent beyond that which would be contemplated by the ordinary user or handler of the product, with the ordinary knowledge common to the community as to the product's characteristics; or**
> >
> > **(2) The user or the handler of the product already knows or reasonably should be expected to know of the characteristic of the product that may cause damage and the danger of such characteristic.**
>
> C. A manufacturer of a product who, after the product has left his control, acquires knowledge of a characteristic of the product that may cause damage and the danger of such characteristic, or who would have acquired such knowledge had he acted as a reasonably prudent manufacturer, is liable for damage caused by his subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

LA. R.S. § 9:2800.57 (emphasis added).

Note the emphasized text above. Vesoulis's decision to omit any reference to *this* subsection – which would be hard to miss, sandwiched as it is between two friendlier provisions that Vesoulis chose to predicate his entire case against ReShape on – is perhaps telling.

But whether he missed it or not, subsection (B) is fatal to any non-preempted state-law claim Vesoulis may have otherwise had under § 9:2800.57. In plain terms, subsection (B) eliminates any duty "to provide an adequate warning" about a product when "The

product is not dangerous to an extent beyond that which would be contemplated by the ordinary user or handler of the product, with the ordinary knowledge common to the community as to the product's characteristics." Id. § 9:2800.57(B)(1). The ordinary users and handlers of the ReShape balloon at issue are bariatric surgeons like Dr. Lavin, and there is no evidence in the record that Dr. Lavin lacked "ordinary knowledge common to [his] community [of physicians] as to the product's characteristics."

To the contrary, the evidence reveals that Dr. Lavin was *quite* familiar with the ReShape balloon and the dangers it could pose to an unfortunate patient. For one, ReShape's Instructions for Use notified Dr. Lavin that the balloon could cause the injury Vesoulis suffered, and the consent form Dr. Lavin prepared for Vesoulis did the same. See ReShape Mot., Ex. A at 5; Dr. Lavin & SSL Mot., Ex. C at 1. For another, Dr. Lavin was clearly aware that esophageal perforation is a common complication of any endoscopy. See Lavin Dep., ReShape Mot., Ex. K.

Without a federal right of action to stand on, and in presumable recognition of the difficulty posed by the LPLA *itself*, Vesoulis attempts to salvage his claims against ReShape by alleging that ReShape "is liable based solely on [its] failure to comply with the [FDA's] PMA Approval Order and applicable FDA regulations." See Second Am. Compl., ¶ 7; Opp'n to ReShape Mot. at 17–18 (fleshing out Vesoulis's allegations in this regard).

But this line of thinking is unimpressive. Clearly, the Court cannot hold on the one hand that Vesoulis's claims are unpreempted state-law claims and on the other hand ignore provisions of the *same* state law that plainly undercut Vesoulis's ability to recover under state-law provisions he claims to "parallel" federal requirements. Federal courts across the nation have consistently disallowed such assertions. Referring to the Supreme Court's holdings in Riegel (see *supra* note 5) and Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), Judge Schiltz forcefully sums up the medical-product-liability plaintiff's challenging task:

> In sum, Riegel and Buckman create a narrow gap though which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the [FDA's organic statute] (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman). For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.

Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

Like countless plaintiffs before him, Vesoulis fails to thread the needle here. Indeed, although ReShape's actions conceivably violated FDA regulations and PMA provisions rooted in the FDCA, they – as detailed above – would *not* afford Vesoulis a plausible basis for recovery under Louisiana state law in the

absence of ReShape's violation of requirements spelled out in FDA regulations and the FDA's PMA Approval Order.

Consequently, because Vesoulis's state-law claims against ReShape "exist solely by virtue of [federal] requirements" enacted as part of a comprehensive regulatory scheme by Congress, they are either preempted by federal law,[7] meritless under Louisiana law,[8] or both. See Buckman, 531 U.S. at 352–53; *supra*.

* * *

Accordingly, for the foregoing reasons, IT IS ORDERED: that the defendants' motions for summary judgment are GRANTED. The plaintiff's informed consent claim against Dr. Lavin and SSL, and the plaintiff's claims against ReShape, are DISMISSED WITH PREJUDICE.

New Orleans, Louisiana, May 12, 2021

MARTIN L. C. FELDMAN
UNITED STATES DISTRICT JUDGE

[7] Because "although Medtronic can be read to allow certain state-law causes of action that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." Buckman, 531 U.S. at 353.

[8] Because LA. R.S. 9:2800.57(B) plainly relieves ReShape of any duty to warn Dr. Lavin about dangers he already "contemplated [as an] ordinary user or handler of the product" at issue.