United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
April 1, 2022
Lyle W. Cayce
Clerk

No. 21-30367

PAUL VESOULIS,

Plaintiff—Appellant,

versus

RESHAPE LIFESCIENCES, INCORPORATED, *formerly known as* ENTEROMEDICS, INCORPORATED; THOMAS LAVIN, M.D.; SURGICAL SPECIALISTS OF LOUISIANA, L.L.C.,

Defendants—Appellees.

Appeal from the United States District Court
for the Eastern District of Louisiana
USDC No. 2:19-CV-1795

Before HIGGINSON, WILLETT, and HO, *Circuit Judges.*

PER CURIAM:*

Appellant Paul Vesoulis sued several defendants in connection with injuries he suffered during the removal of a medical device from his stomach. The district court entered summary judgment for Defendants on some of

* Pursuant to 5TH CIRCUIT RULE 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIRCUIT RULE 47.5.4.

Vesoulis's claims but allowed the remaining claim to proceed to trial. The jury subsequently rendered a verdict for Defendants. Vesoulis now appeals both the verdict and the entry of partial summary judgment. For the reasons explained below, we AFFIRM the district court's judgment in all respects.

I

In 2017, Vesoulis underwent an elective procedure at a Louisiana surgical facility in which an intra-gastric balloon device manufactured by ReShape LifeSciences was placed in his stomach. The device is intended to facilitate weight loss by occupying space in the patient's stomach so as to reduce appetite. Dr. Thomas Lavin performed the procedure, but only after Vesoulis signed a consent form that warned of possible complications. Among them were "Death (very rare)" and "damage to the . . . gastrointestinal tract or intra-abdominal organs including perforation (tearing)."

Consistent with ReShape's instructions for use of the intra-gastric balloon, Vesoulis saw Lavin again six months later in January 2018 to have the device removed via endoscopy. Vesoulis signed another consent form, which warned of possible complications, including a "less than 1 [in] 10,000" risk of "bleeding or perforation of the esophagus, stomach or duodenum." Lavin removed the device on January 11. Vesoulis left the surgical facility with no signs of distress but contacted Lavin later that day complaining of abdominal pain. Lavin ordered a chest x-ray, which was performed the next morning. Based on a radiologist's review of the results, Lavin suspected atelectasis and a pleural effusion requiring emergency surgery. While performing the exploratory laparoscopy in preparation for surgery, however, Lavin found no abnormalities in Vesoulis's esophagus and stomach except for gastric distension. An NG tube was used to relieve the distension and Vesoulis was transferred to the facility's fourth floor while he recovered.

Later that evening, Vesoulis began experiencing swelling and crepitus of the jaw, neck, and clavicle areas. Lavin examined Vesoulis, noting that his respirations were shallow. Lavin ordered an upper GI study, which took place the following morning. On the morning of January 13, Lavin was notified that Vesoulis was having some difficulty breathing. Lavin ordered a STAT CT scan of the chest and neck. The results reflected the presence of air and led to the discovery of a small tear in his esophagus. Lavin repaired the perforation without issue. Afterwards, Vesoulis remained in stable condition and was discharged from the facility on January 19, 2018.

Vesoulis initiated the present litigation in Louisiana state court in January 2019. He sued Reshape and Lavin, as well as Lavin's employer, Surgical Specialists of Louisiana, LLC ("SSL"). Defendants then removed the action to federal district court. Vesoulis's claims against ReShape sounded in product liability and failure to warn. Specifically, Vesoulis alleged that ReShape was "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," referring to LA. STAT. § 9:2800.57(A) and (C). Vesoulis also brought a medical negligence claim against Lavin and SSL, asserting that Lavin failed to "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."

The district court entered summary judgment for Lavin and SSL on Vesoulis's informed-consent claim and for ReShape on his products-liability claim. *See* No. CV 19-1795, 2021 WL 1909725 (E.D. La. May 12, 2021). As for the issue of informed consent, the district court held that Lavin and SSL were entitled to summary judgment because the consent form that Vesoulis

signed before having the intra-gastric balloon inserted into his stomach adequately warned him of the risks of esophageal perforation and death therefrom. The district court held that ReShape was likewise entitled to summary judgment on Vesoulis' failure-to-warn claim because ReShape was shielded from liability by a provision of Louisiana law specifying that

> A manufacturer is not required to provide an adequate warning about his product when [it] 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 . . . the user or 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.

LA. STAT. § 9:2800.57(B). The summary-judgment evidence showed that Lavin was an experienced bariatric surgeon who understood the risks of using ReShape's device, the district court explained, and so the provision quoted above shielded ReShape from liability for failure to warn of those risks. The district court rejected Vesoulis's argument that ReShape's alleged violation of the federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., and associated regulations was a per se violation of a state-law duty of care. The district court reasoned that this theory was foreclosed by Supreme-Court precedent holding that a state-law claim is preempted by federal law if a defendant's conduct would not be actionable under state law but for the fact that the conduct allegedly violated the FDCA and associated regulations.

Vesoulis's medical negligence claim against Lavin and SSL proceeded to trial. The jury ultimately rendered a unanimous verdict for Defendants. Vesoulis appealed both the verdict and the earlier partial summary judgment.

II

We begin by considering the district court's entry of summary judgment for ReShape and partial summary judgment for Lavin and SSL. We review the grant of a motion for summary judgment de novo. *Fennell v. Marion Indep. Sch. Dist.*, 804 F.3d 398, 407 (5th Cir. 2015). Summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact" and that he or she "is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A "dispute about a material fact is 'genuine' . . . 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 district court granted Lavin's and SSL's motion for summary judgment on the informed-consent claim. Vesoulis challenges this grant on appeal, contending that Lavin violated a duty imposed by Louisiana law (or at least that there is a genuine dispute of material fact as to whether Lavin violated such a duty) because he failed to secure Vesoulis's informed consent for the procedures for inserting and removing the intra-gastric balloon device. The law of Louisiana, "both statutory and jurisprudential," requires a physician to secure a patient's informed consent to medical treatment, *Tipton v. Campbell*, 996 So. 2d 27, 36 (La. Ct. App. 2008), but establishes "an evidentiary presumption that a patient's written consent is valid," *Hondroulis v. Schuhmacher*, 553 So. 2d 398, 402 (La. 1988) (citing LA. STAT. § 40:1299.40 (now codified with immaterial changes at LA. STAT. § 40:1157.1)). To overcome this presumption, a plaintiff must "show that: (1) the adverse results of [a procedure] were known, significant, and material risks which should have been disclosed to [the patient] by [the physician]; (2) those risks were not disclosed by [the physician]; (3) [the patient] was

unaware of those risks; and (4) a reasonable person would have refused the [procedure] because of the risks." *Id.* at 404.

Vesoulis argues that Lavin did not adequately warn before inserting the intra-gastric balloon that the procedure could result in esophageal tearing or death. Like the district court, however, we think Vesoulis was so warned. The form he signed before undergoing the procedure clearly alerted him of the possibility of "Death (very rare)" and "[harm to] upper gastrointestinal tract"—of which the esophagus is a part—"or intra-abdominal organs including perforation (tearing)." Vesoulis protests that Lavin was obligated to supplement these warnings by notifying Vesoulis of the two specific deaths to which the ReShape device had been linked. But Louisiana's informed-consent standard has never, to our knowledge, been held to require such fine-grained information; on the contrary, it seems sufficient that the consent form warned of death and accurately noted that such a complication was "very rare." *See Hondroulis*, 553 So. 2d at 404. Vesoulis has identified no Louisiana decisions holding that a physician must disclose the specific number of adverse events that have occurred as a result of a procedure, and we struggle to understand why such data would have been material to a reasonable patient in Vesoulis's position (unless the specific number of deaths were so high as to make the claim that death was "very rare" misleading, which is certainly not the case here). Given that Louisiana law does not require that specific risk percentages be disclosed to patients in order to obtain their informed consent, *see Kennedy v. St. Charles Gen. Hosp. Auxiliary*, 630 So. 2d 888, 892 (La. Ct. App. 1993), there is no reason why the even less useful information of the number of adverse events must be disclosed, either.

The district court said nothing of Vesoulis's other argument regarding informed consent, but we find it equally unpersuasive. Vesoulis contends that, on the consent form he signed before getting the intra-gastric balloon

removed, the risk of esophageal perforation when devices of the same kind were removed via endoscopy was reported as being less than 1 in 10,000, when in fact the risk from the particular ReShape device was 38 in 10,000 (or 1 in 265). But for an informed-consent claim to succeed under Louisiana law, the risk that the defendant failed to disclose must have been material—that is, a risk that would lead a reasonable patient informed of it to decline the procedure. *See Hondroulis*, 553 So. 2d at 403. A factor in determining materiality is whether the procedure was elective, or whether alternatives to it were available. *See id.*; *LaCaze v. Collier*, 434 So. 2d 1039, 1048 (La. 1983). Here, per ReShape's instructions (which were admitted as evidence), "[t]he maximum placement period for the ReShape Dual Balloon is 6 months, and it must be removed at that time or earlier." And as the form Vesoulis signed prior to the device's removal explained, "[t]here are currently no alternatives to removal of the intragastric balloon"—a statement Vesoulis does not contest. The necessity of the procedure and the lack of alternatives make it less likely that a given risk of complication is "material."

Moreover, even if one accepts Vesoulis's argument that Lavin had to disclose the higher risk figure specific to the ReShape device beforehand in order to secure Vesoulis's informed consent to remove it, the risk still would not have been material under Louisiana law. The Louisiana Supreme Court has "held that a .5% possibility of a correctable complication would not be a determining factor to a reasonable patient." *Hondroulis*, 553 So. 2d at 404. Here, Vesoulis suffered a correctable complication, the risk of which (even according to the figures he urges should have been disclosed) was 0.38%. This was not a material risk. All things considered, summary judgment for Lavin and SSL on Vesoulis's informed-consent claim was proper.

* * *

Vesoulis also appeals the district court's entry of summary judgment for ReShape on Vesoulis's failure-to-warn claim. The district court reasoned that, per the applicable Louisiana statute, ReShape is not liable for failure to warn because its intra-gastric balloon was marketed and sold to Lavin, a "user or handler of the product [who] 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." LA. STAT. § 9:2800.57(B). Vesoulis does not dispute the district court's conclusion regarding ReShape's nonliability under Section 9:2800.57(B), but instead argues that ReShape violated the FDCA, 21 U.S.C. § 301 et seq., and associated regulations—which he contends supply a standard of care the violation of which is actionable under Louisiana law.

We believe the district court was right to reject this argument. There is no private right of action to sue for violations of the FDCA or associated regulations. *See Morris v. PLIVA, Inc.*, 713 F.3d 774, 778 (5th Cir. 2013); 21 U.S.C. § 337. Nevertheless, a "claim[] ar[ising] from [a defendant's] alleged failure" to comply with a duty imposed by state law, even if that failure happens to violate the FDCA and regulations issued thereunder, likely raises no preemption concerns so long as the claim is not premised "solely [on] the violation of FDCA requirements." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). But while federal law does not necessarily preempt "state-law causes of actions that parallel [FDCA] requirements," it does preempt "claims [that] exist solely by virtue of . . . [those] requirements." *Id.* at 353. This holding forecloses Vesoulis's claim against ReShape. As we have explained, the court below correctly held that ReShape falls within the protections of LA. STAT. § 9:2800.57(B) and therefore is not liable for failure to warn under Louisiana law. And Vesoulis's attempt to overcome this obstacle by alleging that ReShape violated the FDCA and associated regulations runs headlong into the holdings of *Buckman* and

subsequent cases on preemption.[1] For these reasons, the district court's entry of summary judgment for ReShape was proper.

III

We now consider Vesoulis's appeal of the jury's verdict for Lavin and SSL on Vesoulis's medical negligence claim. Vesoulis argues on appeal that the evidence was so strongly against the verdict that he was entitled to judgment as a matter of law, an issue Vesoulis raised below by unsuccessfully moving for such a judgment pursuant to Federal Rule of Civil Procedure 50(a). "[W]hen a case is tried by a jury, a Rule 50(a) motion is a challenge to the legal sufficiency of the evidence. In resolving such challenges, we draw all reasonable inferences and resolve all credibility determinations in the light most favorable to the nonmoving party." *Foradori v. Harris*, 523 F.3d 477, 485 (5th Cir. 2008) (citations omitted). "[W]e will uphold a jury verdict unless the facts and inferences point so strongly and so overwhelmingly in favor of one party that reasonable men could not arrive at any verdict to the contrary." *Cousin v. Trans Union Corp.*, 246 F.3d 359, 366 (5th Cir. 2001). Moreover, because the "the proper allocation of the burden of proof necessarily implicate[s] the standard of review of a challenge to the sufficiency of the evidence," *Bayle v. Allstate Ins. Co.*, 615 F.3d 350, 358 (5th Cir. 2010), we are mindful of the fact that Vesoulis bore the burden of proving medical negligence under Louisiana law, *see Pfiffner v. Correa*, 643 So. 2d 1228, 1231 (La. 1994).

According to Vesoulis, the jury's verdict cannot stand because the fact that Lavin did not review Vesoulis's x-rays himself, but instead relied on

[1] It makes no difference that the state-law duty at issue here is at least partially established by statute rather than purely by judicial common law. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 379 (5th Cir. 2012).

board-certified radiologists' assessments of the x-rays, establishes as a matter of law that Lavin breached the accepted standard of care in the medical field. At trial, Vesoulis supported his argument to that effect with the testimony of a single expert—and even he vacillated on the issue during cross examination, admitting, "I'm not sure that I would agree that [personally reviewing patients' x-rays] [i]s a standard of care," and, "[i]t would depend" on how one "define[s] 'breach.'" Meanwhile, Defendants offered testimony from three experts who firmly stated their view that Lavin did not breach the standard of care expected of those in his field, either in his reliance on board-certified radiologists' assessment of x-rays or in the course of treatment he administered to Vesoulis. Testimony of this sort is significant, given that Louisiana law places a high premium on expert testimony as evidence of whether a defendant in a medical negligence case violated the applicable standard of care. *See Pfiffner*, 643 So. 2d at 1233.

In our view, the evidence offered at trial as to whether Lavin breached the standard of care quite clearly does *not* "point so strongly and so overwhelmingly in favor" of Vesoulis "that reasonable men could not arrive at [a] verdict" in favor of Lavin and SSL. *Cousin*, 246 F.3d at 366. If anything, the weight of the evidence favors Defendants' position. And even if both sides had presented equally strong evidence, we would still uphold the verdict in observance of our obligation to "draw all reasonable inferences and resolve all credibility determinations in the light most favorable to the nonmoving party"—here, Lavin and SSL. *Foradori*, 523 F.3d at 485. That Vesoulis bore the burden of proof further fortifies our conclusion that he was not entitled to judgment as a matter of law. *See Bayle*, 615 F.3d at 358.

IV

For these reasons, the judgment of the district court is AFFIRMED.