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IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 20-10900

D.C. Docket No. 1:18-cv-23643-UU

CHARLOTTE SALINERO,
DR. EFRAIN SALINERO,

Plaintiffs - Appellants,

versus

JOHNSON & JOHNSON,
ETHICON, INC.,

Defendants - Appellees.

Appeal from the United States District Court
for the Southern District of Florida

(April 29, 2021)

Before LAGOA, ANDERSON and MARCUS, Circuit Judges.

MARCUS, Circuit Judge:

In 2012, Charlotte Salinero underwent surgery to address pelvic organ prolapse. Her doctor, Jaime Sepulveda, implanted Artisyn Y-Mesh, a polypropylene mesh designed and manufactured by Ethicon, Inc. But after surgery, Mrs. Salinero suffered new health issues, which she attributed to the mesh implant. She underwent surgery again to remove it and, with her husband, sued Ethicon and its parent company, Johnson & Johnson, in the Southern District of Florida for failure to warn of the adverse health consequences of an Artisyn Y-Mesh implant (among other claims).

The defendants successfully moved for summary judgment, arguing that Florida's learned intermediary doctrine operates as a complete defense in this case, breaking the chain of causation. The doctrine imposes on medical device manufacturers a duty to adequately warn physicians, rather than patients, of the risks their products pose. The Salineros claim, however, that the doctrine is unavailable to these defendants because Dr. Sepulveda has a long-standing financial relationship with both defendants and thus it was not reasonable for them to expect him to adequately communicate the risks surrounding an Artisyn Y-Mesh implant. The Salineros ask us to create a "financial bias" exception to the learned intermediary doctrine, although the Florida courts have never recognized -- much less discussed -- one.

As a federal court sitting in diversity, we are Erie bound to follow the decisions of the Florida courts. Without any indication from Florida's appellate courts that they would create a "financial bias" exception to the learned intermediary doctrine insofar as it applies to physicians, we hold that the learned intermediary doctrine is available and that, under the facts of this case, it plainly entitles the defendants to summary judgment on the failure-to-warn claim. Dr. Sepulveda's testimony makes it crystal clear that he was both aware of the risks surrounding the Artisyn Y-Mesh implant and stood by his decision to use the implant to treat Mrs. Salinero's prolapse. Under Florida law, an inadequate warning could not be the proximate cause of Mrs. Salinero's injuries and, therefore, the learned intermediary doctrine bars a failure-to-warn claim. Accordingly, we affirm the judgment of the district court.

I.

A.

These are the essential facts surrounding this controversy. In 2012, at the age of 56, Charlotte Salinero suffered from a persistent vaginal bulge and constipation. A doctor referred her to Dr. Jaime Sepulveda, a board-certified surgeon in gynecology, female pelvic medicine, and reconstructive surgery. Dr. Sepulveda diagnosed Mrs. Salinero with pelvic organ prolapse, a potentially debilitating condition where one or more of the pelvic organs -- such as the

bladder, rectum, or uterus -- shift downward into the vagina, and recommended corrective surgery. Over the next few months, Mrs. Salinero's condition worsened into a Stage IV prolapse, the most severe form. Mrs. Salinero's prolapse was so advanced that, at times, her uterus extended outside her vaginal opening.

Mrs. Salinero elected to have surgery, which Dr. Sepulveda and a team of surgeons performed in December 2012 at South Miami Hospital in Miami, Florida. One of the surgeries performed was an abdominal sacrocolpopexy, during which Dr. Sepulveda implanted Artisyn Y-Mesh. Artisyn Y-Mesh is a prescription medical device made out of polypropylene mesh. It is designed and manufactured by Ethicon, Inc., a wholly owned subsidiary of Johnson & Johnson. Artisyn Y-Mesh works as a bridging material, which is implanted through the abdomen to provide support to the pelvic organs. According to Dr. Sepulveda, approximately half of the mesh implant dissolves into the body, while the other half stays in place to provide support to the pelvic organs. Although Dr. Sepulveda discussed the risks of the surgery with Mrs. Salinero, including the risks surrounding the use of a mesh implant, he did not specifically recommend Artisyn Y-Mesh to her. Instead, he unilaterally chose to use it as the implant in the surgery.

A few years after the sacrocolpopexy, Mrs. Salinero began suffering from further health issues, including bleeding, pain, vaginal discharge, bowel obstruction, urinary tract infection, and constipation. In April 2017, a doctor

diagnosed Mrs. Salinero with a rectovaginal vesical fistula -- or connection between organs -- which Mrs. Salinero attributed to the Artisyn Y-Mesh implant. Later that year, she underwent surgery to remove the implant, which was again performed by Dr. Sepulveda and a team of surgeons. Dr. Sepulveda testified that he separated the adhesion within Mrs. Salinero's bladder and rectum, identified the implant, disconnected, dissected, and lifted it out in one piece, but that there were "two little segments underneath that [he] took later on." Despite the removal, Mrs. Salinero continued to suffer from permanent, debilitating health complications, including fecal incontinence, small bowel obstructions, chronic pain, and dyspareunia (pain during intercourse), which she alleges are due to the Artisyn Y-Mesh.

B.

On September 6, 2018, the Salineros sued Ethicon and Johnson & Johnson in the United States District Court for the Southern District of Florida. They alleged that a polypropylene mesh is "biologically incompatible with human tissue and promotes an immune response in a large subset of the population[,] . . . [which] promotes degradation of the polypropylene mesh, as well as the pelvic tissue, and can contribute to the formation of severe adverse reactions." They also lodged several product liability claims against the defendants, though only one --

failure to warn -- is relevant in this appeal.[1] The Salineros claimed that at the time of the surgery, the Artisyn Y-Mesh Instructions for Use ("IFU") failed to properly and adequately warn of the risks related to the implantation and use of the Artisyn Y-Mesh and, therefore, the defendants were strictly liable for Mrs. Salinero's injuries.

In May 2019, the defendants moved for summary judgment. As for the failure-to-warn claim, the defendants argued that under Florida law they only had a duty to warn the physician -- in this case, Dr. Sepulveda -- rather than Mrs. Salinero, and that they properly discharged their duty. In support, they cited to Dr. Sepulveda's deposition, in which he testified that he believed he was fully apprised of the risks of implanting Artisyn Y-Mesh before Mrs. Salinero's surgery. He unambiguously said that he viewed his December 2012 decision to use Artisyn Y-Mesh in Mrs. Salinero's surgery as an appropriate one, even knowing exactly what adverse effects she developed after the surgery. When asked whether he stood by his decision to use Artisyn Y-Mesh with Mrs. Salinero, he responded, "[y]es." When asked whether he still believed that the surgery he performed in December 2012 was the "best option" for Mrs. Salinero, again he said "[y]es." And when asked if he thought "that the sacrocolpopexy with ArtisynTM Y-Mesh was a safe

[1] The Salineros brought nine claims in all: negligence, manufacturing defect, design defect, failure to warn, false information negligently supplied for the guidance of others, negligent infliction of emotional distress, gross negligence, loss of consortium, and punitive damages.

and effective surgery for Mrs. Salinero," he again responded, "[y]es, I believe that." Dr. Sepulveda explained that Artisyn Y-Mesh remained his "preferred implant" for similar surgeries and that he would use Artisyn Y-Mesh for an implant at the next opportunity.

The Salineros opposed the motion, urging that Dr. Sepulveda was not an "objective" practitioner and therefore his testimony should not be relied upon to establish the learned intermediary defense. For support, they pointed to Dr. Sepulveda's long-running relationship with both Ethicon and Johnson & Johnson, a relationship that goes back decades and has been very lucrative to Dr. Sepulveda. The record shows that Dr. Sepulveda served as an expert witness for Ethicon in over 20 cases and as a consultant on product evaluations, mesh product trials, and training programs. Dr. Sepulveda also reviewed cases and performed consulting work for Johnson & Johnson. He admitted to earning some $2 million from Johnson & Johnson over the course of his career. He explained that he does this work for the defendants "to continue training" and "to understand the anatomy better and to keep [himself] in shape for all the surgeries." There is no evidence that Dr. Sepulveda performed any work for either Ethicon or Johnson & Johnson specifically related to Artisyn Y-Mesh.

The Salineros argued that this uncontested evidence demonstrated that Dr. Sepulveda was biased toward the defendants, therefore barring the application of

the learned intermediary doctrine as an affirmative defense. They also claimed that there were triable issues of fact as to Dr. Sepulveda's knowledge, the adequacy of the IFU warnings, and whether Dr. Sepulveda actually would have prescribed Artisyn Y-Mesh if he had received adequate warnings.

The district court acknowledged that Florida's courts have not treated the learned intermediary as a complete defense, noting that "a bright-line rule that Florida's learned intermediary doctrine always applies to bar failure-to-warn claims in cases involving prescription medical devices" would be inappropriate. However, the court predicted that the Florida Supreme Court would not recognize a "financial bias" exception to the doctrine based solely on proof of some financial relationship between the physician and the manufacturer, and, therefore, granted summary judgment to the defendants on the failure-to-warn claim.

The case proceeded to trial on the remaining claims. The jury returned a unanimous verdict for Ethicon.[2] The Salineros filed a timely appeal, only raising issues related to the failure-to-warn claim.[3]

[2] The district court dismissed Johnson & Johnson as a defendant after the company stipulated it was not involved in the design or manufacture of Artisyn Y-Mesh.

[3] The Salineros also appeal a decision by the district court excluding their medical expert, Dr. Michael Margolis, on the grounds that he was not qualified to testify about the adequacy of the Artisyn Y-Mesh IFU. Without this testimony, the district court held, as an alternative ground for summary judgment, that the plaintiffs could not meet their burden of establishing that the defendants' warnings were inadequate. Because we hold that the defendants were entitled to summary judgment as a matter of law based on the learned intermediary doctrine, we do not

II.

"We review a district court's grant of summary judgment de novo, viewing the evidence and drawing all reasonable inferences in the light most favorable to the nonmoving party." Hubbard v. Bayer HealthCare Pharms. Inc., 983 F.3d 1223, 1232 (11th Cir. 2020). Summary judgment is appropriate only 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). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." Tesoriero v. Carnival Corp., 965 F.3d 1170, 1177 (11th Cir. 2020) (quotation marks and citation omitted).

A.

In this diversity action, Florida law applies to the Salineros' failure-to-warn claim. To succeed on a failure-to-warn claim, the "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 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)).

reach the issue whether the district court abused its discretion in excluding Dr. Margolis's testimony.

However, in cases involving medical products like Artisyn Y-Mesh, "the duty of [a device] manufacturer to warn of dangers involved in [the] use of a [device] is satisfied if [it] gives adequate warning to the physician who prescribes [the device]." Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 823 (Fla. 5th DCA 1981) (quotation omitted); see also Eghnayem, 873 F.3d at 1321. The physician acts as a "learned intermediary" between the manufacturer and the patient, "weighing 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. Thus, in order to satisfy the causation requirement in a medical device failure-to-warn claim, "a plaintiff must show that her treating physician would not have used the product had adequate warnings been provided." Id.

The learned intermediary doctrine is a longstanding feature of Florida law, first recognized by the Fifth District Court of Appeal in 1981. In Buckner v. Allergan Pharmaceuticals, the court held that a "manufacturer of a dangerous commodity, such as a drug, does have a duty to warn but when the commodity is a prescription drug . . . this duty to warn is fulfilled by an adequate warning given to those members of the medical community lawfully authorized to prescribe, dispense and administer prescription drugs." 400 So. 2d at 822. The court emphasized that the physician acted as learned intermediary because of the physician's duty to "inform himself of the qualities and characteristics of those

products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product." Id. at 823 (quotation omitted).

The Florida Supreme Court first acknowledged the learned intermediary doctrine in 1989, citing Buckner approvingly. Florida's high court described the doctrine -- and the special role of the physician as an intermediary between the manufacturer and the patient -- this way:

> At the outset, it is clear that the manufacturer's duty to warn of [a prescription drug]'s dangerous side effects was directed to the physician rather than the patient. This is so because the prescribing physician, acting as a "learned intermediary" between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs.

Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989). Thus, the manufacturer's adequate warning to a physician breaks the causal chain and precludes a failure-to-warn claim.

The causal chain may still be broken even if the manufacturer provides an inadequate warning so long as the physician is aware of the risks or would still recommend the device despite those risks. In Hoffmann-La Roche Inc. v. Mason, 27 So. 3d at 77, the plaintiff argued that "the warning label was inadequate to warn physicians that" Accutane, the prescription drug, could lead to the plaintiff developing inflammatory bowel disease ("IBD"). But Florida's First District Court of Appeal explained that "the prescribing physician[] testified that he understood

the warning label to mean that there was at least a possibility of a causal relationship between Accutane and IBD," and that "he would still be willing to prescribe Accutane to his patients even if there was evidence showing that it could cause IBD in rare cases." Id. In fact, the physician "also testified that even if the warning label contained all of the information suggested by [the plaintiff]'s expert, he would still have prescribed the medication" for the plaintiff. Id. The court concluded that "any inadequacies in Accutane's warning label could not have been the proximate cause of [the plaintiff]'s injury because [the physician] understood that there was a possibility that use of the drug could lead to [the plaintiff] developing IBD and he made an informed decision to prescribe the drug for [the plaintiff] despite this risk." Id.

The Salineros allege that the defendants' IFU was inadequate; however, Dr. Sepulveda's testimony shuts down that line of attack. As he clearly stated in his deposition, an improved IFU would not have changed his choice of implant for the surgery. When asked about the Artisyn Y-Mesh IFU, Dr. Sepulveda explained that he did not rely on it as the primary source of information on the risks associated with Artisyn Y-Mesh and that instead he relied primarily on other sources:

> Q. When you decide what type of surgery to do to treat a particular patient's prolapse, what sources of information do you rely on?

> A. I rely on the published data, obviously on my training, my textbooks, journals, Cochrane reviews[4] . . . society recommendation[s], society opinions.

Dr. Sepulveda was also clear that an IFU containing more information on the risks posed by Artisyn Y-Mesh would not have altered his decision to use the implant in Mrs. Salinero's surgery:

> Q. And we discussed other -- or the potential risks that you were aware of back in December 2012. And if the ArtisynTM IFU would have specifically, you know, included the risks that you were aware of from your review of the literature and other materials, including your experience, would that have changed your decision to use ArtisynTM Y-Mesh with Mrs. Salinero?
>
> A. No.

Furthermore, and perhaps most importantly, Dr. Sepulveda provided explicit, uncontroverted testimony that he believed his decision to use Artisyn Y-Mesh as the mesh implant for Mrs. Salinero's surgery was correct. See, e.g., Hubbard, 983 F.3d at 1233 (holding that the learned intermediary doctrine applied under Georgia law when the physician testified that he would have prescribed the drug even with the improved label information); Small v. Amgen, Inc., 723 F. App'x 722, 725 (11th Cir. 2018) (explaining that the learned intermediary doctrine "typically" applies under Florida law when a physician "has actual knowledge of

[4] Dr. Sepulveda explained that a Cochrane review is "a scientific collaboration that examines the efficacy and the safety complications of the different procedures that [physicians] have."

the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided") (quotation omitted). Dr. Sepulveda repeated that he stood by his decision to use Artisyn Y-Mesh for Mrs. Salinero and still believed that the surgery he performed in December 2012 was the "best option" for her. He also explained that Artisyn Y-Mesh remained his "preferred implant" for similar surgeries. Indeed, he said, that if he were "doing a sacrocolpopexy this afternoon," he would still use that implant. His testimony unequivocally establishes that he would have used the Artisyn Y-Mesh implant for Mrs. Salinero's sacrocolpopexy regardless of the risks included in the Artisyn Y-Mesh IFU.

Just like in Mason, Dr. Sepulveda's testimony reveals that any claimed inadequacies in the Artisyn Y-Mesh IFU could not have been the proximate cause of Mrs. Salinero's injuries. 27 So. 3d at 77. The district court, therefore, properly determined that the learned intermediary doctrine was a complete defense to the failure-to-warn claim.

B.

Nevertheless, the Salineros argue that the learned intermediary doctrine is unavailable here because of the uncontested evidence of a financial relationship between Dr. Sepulveda and the defendants. They claim that there is a "financial bias" exception to the learned intermediary doctrine "where, as here, financial ties

between the treating physician and the manufacturer defeat the assumption of objectivity underlying the defense."

The trouble with the argument is that no Florida court, as best we can tell, has ever recognized, let alone adopted, a "financial bias" exception to the learned intermediary doctrine with respect to prescription drugs or medical devices used by a physician. Indeed, neither party has cited to any Florida case abandoning the doctrine on account of a financial relationship between a physician and a manufacturer of a medical device or a prescription drug. For us to create a wholly new doctrine, virtually out of whole cloth, would work a profound change in Florida's law. Sitting in diversity, we are Erie bound to follow Florida's courts as they expound on tort law and nothing we can discern in Florida's case law would suggest, let alone enable us to predict, this is a path its courts are likely to go down.

For starters, the "financial bias" exception is not a legal term of art. Instead, the Salineros use the name to refer to a handful of decisions in which federal courts sitting outside of Florida and outside of this Circuit have declined to apply the learned intermediary doctrine because there was some evidence suggesting a physician was biased toward the drug or device manufacturer. The Salineros primarily rely on In re: DePuy Orthopaedics, Inc., No. 3:11-MD-2244-K, 2016 WL 6268090, *6 (N.D. Tex. Jan. 5, 2016), In re Vioxx Prods. Liab. Litig., MDL No. 1657, 2015 WL 1909859, at *9 (E.D. La. Apr. 21, 2015), and Murthy v. Abbott

Lab'ys, 847 F. Supp. 2d 958, 964, 971–73 (S.D. Tex. 2012). But none of these cases arose under Florida law and none of them suggest that Florida's courts would create, let alone apply, a "financial bias" exception to the learned intermediary doctrine as applied to physicians.

Nor do these cases represent the prevailing approach taken by other courts in other jurisdictions on this issue. In fact, as best we can tell, other federal courts faced with the opportunity to apply some kind of a "financial bias" exception to a physician have declined to do so absent some indication from a state court that such an exception even exists. See, e.g., Calisi v. Abbott Lab'ys, No. CA 11-10671-DJC, 2013 WL 5462274, at *3 (D. Mass. Feb. 25, 2013); DiBartolo v. Abbott Lab'ys, 914 F. Supp. 2d 601, 616 (S.D.N.Y. 2012). Still other courts, sitting in diversity jurisdiction, have refused to consider whether such an exception would be appropriate under state law without proof of bias beyond evidence of compensation. See, e.g., Talley v. Danek Med., Inc., 179 F.3d 154, 163–64 (4th Cir. 1999); In re Trasylol Prods. Liab. Litig.-MDL-1928, No. 08-MD-01928, 2011 WL 2117257, at *4 (S.D. Fla. May 23, 2011); In re Zyprexa Prods. Liab. Litig., No. 04-MD-1596, 2010 WL 348276, at *11 (E.D.N.Y. Jan. 22, 2010); Miller v. Pfizer Inc. (Roerig Div.), 196 F. Supp. 2d 1095, 1129 n.108 (D. Kan. 2002), aff'd sub. nom. Miller v. Pfizer, Inc., 356 F.3d 1326 (10th Cir. 2004).

Over almost four decades, Florida's courts have applied the learned intermediary doctrine to failure-to-warn cases involving physicians who administer medical drugs and devices to their patients. The Salineros would have us create a new rule largely based on the case of Aubin v. Union Carbide Corp., 177 So. 3d 489 (Fla. 2015), which dealt with a bulk asbestos supplier who sold asbestos to intermediary manufacturers for use in construction products.

The problem with the citation to Aubin is that the case did not involve a prescription drug or a medical device prescribed by a physician for a patient. In no way did it implicate the physician-patient relationship, nor did the Florida Supreme Court borrow from Florida's medical learned intermediary cases in reaching its decision. Instead, it drew its support from other decisions involving an asbestos manufacturer-supplier and an intermediary-manufacturer. Id. at 514–16. Nothing in the Aubin decision addresses or purports to overturn the analysis in Felix or the decisions of Florida's intermediate appellate courts opining on the quite different circumstances surrounding physicians and their patients.

In Aubin, the supplier "specifically marketed its product to intermediary manufacturers for use of the asbestos in products" and "was not involved in the formulation, packaging, or sale of the end products." Id. at 496. On appeal, the Florida Supreme Court confirmed the availability of the learned intermediary doctrine as a defense, but also noted that in this context the doctrine "is not a

complete defense," looking to both the Second and Third Restatement of Torts. Id. at 514–15. Under this approach, "the critical inquiry is whether the manufacturer was reasonable in relying on the intermediary to fully warn the end user and whether the manufacturer fully warned the intermediary of the dangers in its product." Id. at 515. It concluded that "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." Id. The Salineros argue that Aubin generally "holds that an intermediary's financial bias can defeat the learned intermediary defense," which is consistent with the use of the "financial bias" exception in DePuy. But Aubin does not go that far, and in any event, it arises in a sharply different context.

Until Florida's appellate courts tell us otherwise, as we see it, a physician who has significant education and training and understands the complexity of a medical drug or device is in a profoundly different position than an intermediary manufacturer of construction materials that include asbestos. In this case, and on this record, we are satisfied that Dr. Sepulveda did just what is expected of physicians. He used his individualized medical judgment to determine what treatment to offer Mrs. Salinero. As he explained, polypropylene mesh was the "current clinical standard" for the treatment of prolapse because it offered the best

results when used in sacrocolpopexy. This was because of its durability, porosity, and lower rate of revision compared to alternative implants and procedures. And when Mrs. Salinero's prolapse worsened, he concluded that "conservative measures" would not be available to treat her problems; instead, a mesh implant would be necessary as reinforcement.

To read Aubin as having overturned Florida's extensive precedent and to hold today that Florida law recognizes a "financial bias" exception in this context would amount to a sea change in the state's product liability law. It would upend how Florida's courts have considered failure-to-warn claims and the role of the physician as a learned intermediary. Without some indication that Florida intends to recognize so significant a change in the law, a federal court sitting in diversity ought not to do so. See, e.g., Alexander Proudfoot Co. World Headquarters v. Thayer, 877 F.2d 912, 916 (11th Cir. 1989) (explaining that a federal court sitting in diversity must apply the law of the state so that "federal decisions mirror those of a court in the forum state"); see also Nicolaci v. Anapol, 387 F.3d 21, 27 (1st Cir. 2004) ("Federal courts sitting in diversity should be cautious about pushing state law to new frontiers.") (quotation omitted and alterations accepted); Associated Int'l Ins. Co. v. Blythe, 286 F.3d 780, 783 (5th Cir. 2002) ("When making an Erie-guess in the absence of explicit guidance from the state courts, we must attempt to predict state law, not to create or modify it.") (quotation omitted);

Lexington Ins. Co. v. Rugg & Knopp, Inc., 165 F.3d 1087, 1092 (7th Cir. 1999) (explaining that "a federal court sitting in diversity must proceed with caution in making pronouncements about state law"). Until then, we are obliged to apply the learned intermediary doctrine as it has been pronounced by the Florida Supreme Court. In this case, the learned intermediary doctrine bars the failure-to-warn claim.

We AFFIRM.