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Eleventh Circuit Reaffirms Florida's Learned Intermediary Doctrine in Failure-to-Warn Case

On April 29, 2021, the Eleventh Circuit Court of Appeals issued a significant decision reaffirming Florida's learned intermediary doctrine applies to prescription medical devices, rejecting a "financial bias" challenge, and making clear that an adequate set of warnings in the Instructions for Use (IFU) to the physician will preclude a failure-to-warn claim against the manufacturer. Florida has long recognized the learned intermediary doctrine, which provides that "the manufacturer's duty [to warn] runs to the physician, rather than the patient." *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1365 (S.D. Fla. 2007) (applying the learned intermediary doctrine to the prescription medical device context) (internal citation omitted). Defendants sometimes argue that a manufacturer satisfies its duty to warn the physician by providing the IFU.

In *Salinero v. Johnson & Johnson*, Case No. 20-10900 (11th Cir. 2021), the plaintiff underwent a pelvic mesh implant and explant, and sued in the Southern District of Florida for, among other claims, failure to warn. Defendants moved for summary judgment on that claim. Plaintiffs (the patient and her husband) argued the learned intermediary doctrine should not apply because the operating surgeon had "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 [the 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." Plaintiffs noted that the doctor had decades-long relationships with both defendants, earned over $2 million from one, served as an expert witness for the other in more than 20 cases, and served as an expert consultant for both.

The case is also noteworthy for reciting the history of the learned intermediary doctrine in Florida, going back to 1981. Its review of Florida law led it to squarely reject the invitation to make a "sea change in the state's product liability law":

> 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. [The doctor's] testimony makes it crystal clear that he was both aware of the risks surrounding the [ ] 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.

The court acknowledged that adequacy of warnings (including IFUs) could be a fact issue precluding summary judgment in certain cases, but pointed out that 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." And that was the case here: "The Salineros allege that the defendants' IFU was inadequate; however, [the doctor'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."

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