

# Salinero v. Johnson & Johnson et al.

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## WHY IT MADE THE LIST

The term “learned intermediary” originated in the Eighth Circuit decision of *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966)<sup>1</sup> and today is applied in most U.S. jurisdictions to define the warning obligations for prescription drug and device manufacturers. In broad terms, this doctrine stands for the proposition that a manufacturer fulfills its duty of care when it provides all necessary information to a “learned intermediary” who then interacts with the consumer of a product. Where the learned intermediary doctrine applies, the duty to warn and adequacy of warnings are more easily defended against failure-to-warn claims. Over the last fifty-six years, plaintiffs consistently have attempted to avoid the learned intermediary doctrine and pursue failure-to-warn claims without having to deal with the doctrine’s limiting effect.

Prior to *Salinero v. Johnson & Johnson*, no Florida court had specifically addressed whether a physician’s financial relationship with a manufacturer could alter the doctrine.<sup>2</sup> As in other places, in Florida, where prescription drugs and devices are accompanied by an adequate set of warnings in the Instructions for Use (IFU) to the physician, failure-to-warn claims fail against their manufacturers. The Eleventh Circuit has found the learned intermediary doctrine still applies, even where a physician has a financial relationship with the manufacturer.

## DISCUSSION

### *Legal Background*

Failure-to-warn claims in a prescription product context are almost universally adjudicated by application of the learned intermediary doctrine and frequently at an earlier stage in the litigation, depending on various factors and most often after a physician’s testimony. Under the doctrine, courts evaluate the adequacy of product labeling by reference to the understanding of the prescriber rather than the patient. While some failure-to-warn claims are barred by application of other dispositive legal

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<sup>1</sup> Carole A. Cheney, *Not Just for Doctors: Applying the Learned Intermediary Doctrine to the Relationship between Chemical Manufacturers, Industrial Employers and Employees*, 85 NW. U. L. REV. 562, 581 n. 127 (1991).

<sup>2</sup> *Salinero v. Johnson & Johnson et al.*, 995 F.3d 959, 961 (11th Cir. 2021) (The Eleventh Circuit recognized that the “Salineros asked [the district court] to create a ‘financial bias’ exception to the learned intermediary doctrine, [but] the Florida courts [had] never recognized—much less discussed—one.”).

defenses (primarily preemption), when prescription product cases get to the point of evaluation, the key from a warning perspective is often the testimony of the prescribing physician.

The Restatement (Second) of Torts expresses the basic requirements for a plaintiff to plead and prove a failure-to-warn claim. A plaintiff must allege and establish 1) the manufacturer either knew, or should have known, of dangers inherent in the use of the product, yet adequate warnings were not given; and 2) if adequate warnings had been provided, the harm would have been avoided.<sup>3</sup> Thus, the first point of dispute is almost always whether the product is “properly prepared, and accompanied by proper directions and warnings.”<sup>4</sup> In the prescription product context, the manufacturer must make adequate warnings available to the patient’s doctor—not to the patient—since physicians are in a better position to understand the risks and also initiate the decision for the patient to use the prescription product.<sup>5</sup> Here, the physician is the learned intermediary.<sup>6</sup>

The second part is the causation element, asking whether different warnings would have resulted in a different outcome. Proximate cause is essential for survival of failure-to-warn claims. If the learned intermediary does not read the label, plaintiff cannot show proximate cause, and the warning claim fails.<sup>7</sup> For example, a patient’s widow alleged her husband’s prescription antidepressants did not adequately warn his physician of the associated side effects. Because the physician admitted he had not read the label, the widow failed to show that the alleged inadequate warnings proximately caused her husband’s death.<sup>8</sup> So ended the failure-to-warn claim, regardless of the warning’s contents.

What has not been addressed uniformly is whether a plaintiff can successfully diminish the value of the learned intermediary doctrine and create a question of fact for the jury by showing evidence that the manufacturer incentivized the physician to ignore the warnings and stay the course with the allegedly “dangerous device.” *Salinero v. Johnson & Johnson et al.* refuses to expand Florida law to accommodate this proposed exception following the logic of other jurisdictions considering similar arguments.

### *Factual Background*

Ethicon’s Artisyn® pelvic mesh is a prescription device indicated to treat pelvic organ prolapse. The Food and Drug Administration cleared Ethicon’s premarket notification for Artisyn® pelvic mesh as a Class II medical device in June 2012.<sup>9</sup>

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<sup>3</sup> Restatement (Second) of Torts § 402A cmt. j.

<sup>4</sup> Restatement (Second) of Torts § 402A cmt. k.

<sup>5</sup> *Reyes v. Wyeth Labs., Inc.*, 498 F.2d 1264, 1276 (5th Cir. 1974) (“Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers[.]”).

<sup>6</sup> *See id.*

<sup>7</sup> *E.g.*, *Motus v. Pfizer Inc. (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004).

<sup>8</sup> *Id.* at 661.

<sup>9</sup> CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., K113205, ETHICON 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION (June 12, 2012), [https://www.accessdata.fda.gov/cdrh\\_docs/pdf11/K113205.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf11/K113205.pdf).

### A. Court Decision

In *Salinero v. Johnson & Johnson et al.*, plaintiff Charlotte Salinero sued Johnson & Johnson and its subsidiary, Ethicon, on September 6, 2018, in the U.S. District Court for the Southern District of Florida for alleged injuries from Ethicon’s Artisyn® pelvic mesh.<sup>10</sup> She alleged the Artisyn® pelvic mesh Dr. Jaime Sepulveda implanted in 2012 had to be removed five years later because of fistulas, fecal incontinence, and severe pain.

Plaintiff alleged Ethicon was liable under theories of negligence, strict liability based on manufacturing defect, strict liability based on design defect, failure-to-warn, false information negligently supplied for guidance of others, negligent infliction of emotional distress, gross negligence, and loss of consortium.

Like many past failure-to-warn claims in the prescription device space, Salinero’s failure-to-warn claim fell short upon application of Florida’s learned intermediary doctrine. But it was Salinero’s novel “financial bias” argument that drove the Southern District of Florida to take a harder look at Salinero’s failure-to-warn claim.

Ethicon argued the learned intermediary doctrine barred Salinero’s failure-to-warn claim. In his deposition, Dr. Sepulveda testified that he mainly relies on his experience and training when choosing an appropriate implantable device. He also testified that he was aware of the potential risks with Ethicon’s Artisyn® pelvic mesh but considered the risks to be highly infrequent. And at some point prior to its use, Dr. Sepulveda read the Instructions for Use and determined that Ethicon’s Artisyn® pelvic mesh was still the best option for Salinero. When a physician testifies to reading the IFU of a challenged medical device, and where the IFU warns of the risk alleged, the link between a manufacturer and plaintiff is fractured.

Salinero attempted to sidestep the learned intermediary doctrine by arguing that it does not apply when the manufacturer financially incentivizes the physician to disregard the dangers and stay the course. She specifically relied on *Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 514 (Fla. 2015), contending that Dr. Sepulveda’s judgment was clouded by his significant financial relation with Ethicon and the fact that Ethicon had long used him as an expert witness and consultant, thus wrongfully casting aside Artisyn®’s risks of failure.

The plaintiff in *Aubin* claimed the manufacturer failed to warn its retailers of the significant harm attached to its asbestos. The Florida Supreme Court viewed the manufacturers warnings in light of the product’s degree of danger: the greater the harm the end user would face if the manufacturer did not give proper warnings, the less reasonable a manufacturer would be in relying on an intermediary to ensure the warnings were fully and adequately communicated to the end user.<sup>11</sup> The degree of harm and reasonability of the manufacturer’s reliance on the retailers created a question of fact left to the jury, thus escaping dismissal as a question of law.

But the Florida Supreme Court in *Aubin* passively—and seemingly tangentially to the facts—provided 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

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<sup>10</sup> Johnson & Johnson was dismissed from the case leaving Ethicon as the sole defendant.

<sup>11</sup> *Salinero v. Johnson & Johnson et al.*, 400 F. Supp. 3d 1334, 1346 (S.D. Fla. 2019), *aff’d*, 995 F.3d 959 (11th Cir. 2021) (citing *Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 515–16 (Fla. 2015)).

intermediary to withhold the necessary information from the consumer.”<sup>12</sup> Salinero read this to mean the Florida courts adopted “financial bias” as a reason to cast aside the learned intermediary doctrine, but the Southern District of Florida declined to adopt her medical device comparison to *Aubin*’s asbestos suit. Thus, the district court dismissed Salinero’s failure-to-warn claim.<sup>13</sup>

After a trial in January 2020—in which the jury rejected all of Salinero’s remaining claims against Ethicon—Salinero sought to revive her case by appealing the U.S. District of Florida’s dismissal of the failure-to-warn claim. She argued that Dr. Sepulveda’s undisclosed financial relationship with Ethicon pierced Ethicon’s defense that it did not have a duty to warn her directly. Stated another way, plaintiff argued the district court had erred when it applied the learned intermediary doctrine to dismiss the failure-to-warn claim.

The Eleventh Circuit reviewed the judgment as a matter of law de novo, evaluating Salinero’s novel financial bias argument.<sup>14</sup> Emphatically, the Eleventh Circuit held that Florida courts have never recognized a “financial bias” exception to the learned intermediary doctrine on prescription drug or medical devices used by a physician, and the Eleventh Circuit was not willing to create new doctrine out of whole cloth.<sup>15</sup>

While *Aubin* created an exception to the learned intermediary doctrine, it did not implicate the physician–patient relationship, nor did the Florida Supreme Court borrow from Florida’s medical learned intermediary cases in reaching its decision.<sup>16</sup> The Eleventh Circuit further differentiated the physician’s degree of sophistication from that of an asbestos manufacturer:

[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.<sup>17</sup>

Salinero’s failure-to-warn claim could not succeed because Dr. Sepulveda testified he knew the risks posed by Ethicon’s Artisyn® pelvic mesh but still chose it over other options.<sup>18</sup> Because Dr. Sepulveda knew the risks the prescription device posed, the Eleventh Circuit denied Salinero’s effort to rewrite the learned intermediary doctrine, rejecting her “financial bias” argument and dismissing her failure-to-warn claim.

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<sup>12</sup> *Aubin*, 177 So. 3d at 515 (emphasis added).

<sup>13</sup> *Salinero*, 400 F. Supp. at 1347.

<sup>14</sup> *Salinero v. Johnson & Johnson et al.*, 995 F.3d 959, 964 (11th Cir. 2021).

<sup>15</sup> *Id.* at 967.

<sup>16</sup> *Id.* at 967–68.

<sup>17</sup> *Id.* at 968.

<sup>18</sup> *Id.* at 965–66 (upholding summary judgment where doctor testified that different warning would not have changed his decision to implant the device); *In re DePuy Orthopaedics, Inc.*, 888 F.3d 753, 775 (5th Cir. 2018) (testimony of treating physician must show that different warning would have changed prescribing decision); *Higgins v. Ethicon*, No. 2:12-CV-01365, 2017 WL 2813144, at \*3 (S.D. W. Va. Mar. 30, 2017) (summary judgment where no evidence that different warning would have changed prescriber’s decision); *Twombly v. Bos. Sci. Corp.*, No. 2:13-CV-23829, 2016 WL 1737118, at \*6 (S.D. W. Va. May 2, 2016) (same).

## IMPACT OF THE DECISION

*Salinero* underscores the Eleventh Circuit's understanding of the rationale behind the learned intermediary doctrine:

[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.<sup>19</sup>

In other words, the financial interests of the physician should not overcome the dispositive impact of the learned intermediary doctrine. The court left open the question of whether certain extraordinary circumstances might keep a court from granting summary judgment based on the doctrine or whether certain influence might be deemed to take away that independent medical judgment. Unlike professionals in some other industries, physicians are well-educated, highly trained, and have a great deal of supervision over their patients and are oath-bound to act in the best interests of such patients based on their medical needs. At the same time, a manufacturer most often has little opportunity to provide direct warnings and certainly does not have or provide the necessary medical judgment to apply to a patient's particular case. While plaintiffs will likely continue to test the learned intermediary doctrine and explore whether some financial relationship evidences undue influence, the financial interests of the physician alone may never outweigh the longstanding precedent of the learned intermediary doctrine.

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<sup>19</sup> *Salinero*, 995 F.3d at 968.