

[PUBLISH]

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 --

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.