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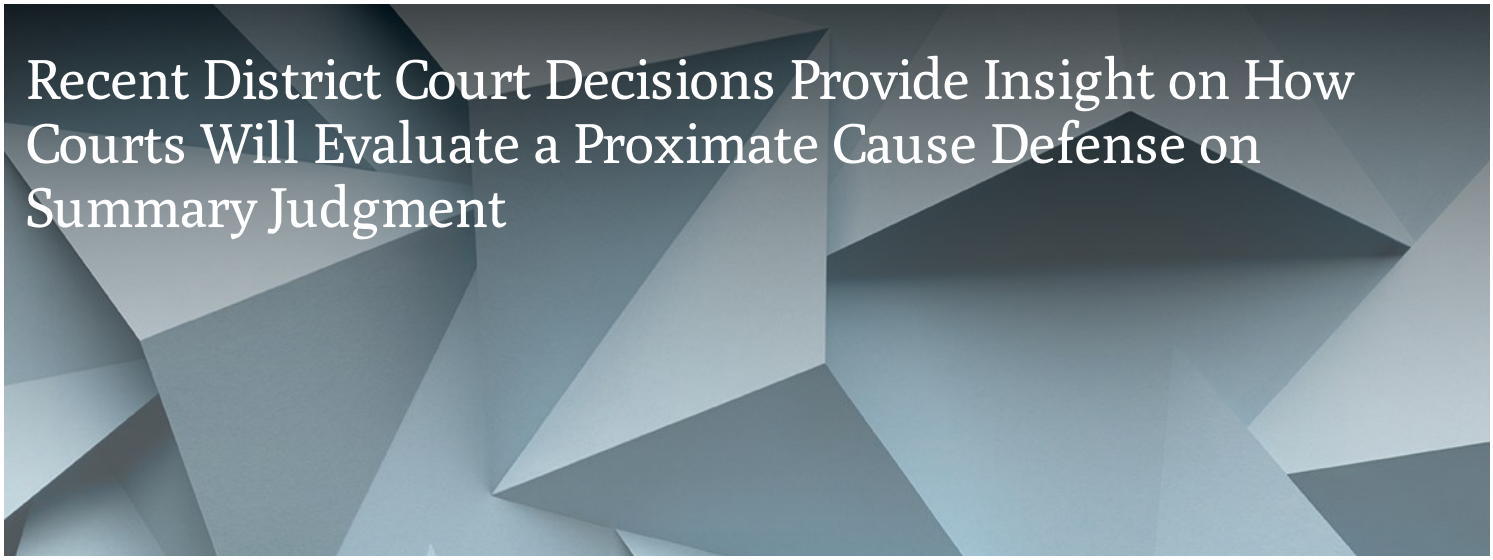
BLOG

Recent District Court Decisions Provide Insight on How Courts Will Evaluate a Proximate Cause Defense on Summary Judgment



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In two recent cases involving medical device implants, two federal courts ruled on defendants' summary judgment motions on failure to warn claims—one court granting and the other denying. In both cases, the defendant argued that the alleged failure to warn did not proximately cause the plaintiff's injury, i.e., an additional warning would not have had any impact on the way the doctor treated the patient. The cases—and the differing results—shed light on which facts and theories defense counsel should seek to develop during discovery to succeed on summary judgment.

In *Ellis v. Ethicon, Inc.*, 2021 WL 2949779, at *1 (W.D. Wash. July 14, 2021), the plaintiff suffered allegedly undisclosed adverse side effects, including chronic sharp pelvic and nerve pain after being implanted with a "TVT"—a prolene mesh implant manufactured by defendant.

The court granted the defendants' motion for summary judgment on plaintiffs' failure to warn claim after finding that the plaintiffs could not establish proximate cause because of the operating physician's "prior knowledge of the risks of injuries." *Id.* at *4. Specifically, the court relied on the physician's testimony that he "was aware of the risks of injuries that [plaintiff] asserts she suffers from." *Id.*

Further, the court found that the plaintiffs did not "present[] any non-speculative evidence that [the operating physician] would have taken a different course of action if additional warnings were given to him." *Id.* The operating physician testified that "if any additional risks were disclosed to him within any literature, such as patient brochures, he would have passed the information on to the patient." *Id.* at *2. However, the court found that this testimony was insufficient evidence to establish that the operating physician would have actually acted differently if additional warnings had been provided. *Id.* at *4. The court reasoned that "his testimony was not that the new information would have altered his decision to recommend the [device] to [plaintiff]" and the testimony was "not a conditional statement about whether he would have taken a different course of action in recommending the [device] to [plaintiff's wife] as Plaintiffs conten[d]." *Id.* ("The evidence provided by Plaintiffs speculates as to what [the operating physician] would have done if he was given additional warnings."). "The uncontroverted evidence is simply that [the operating physician] would have informed [plaintiff's wife] of the additional risks, not that he 'would have treated the product differently and avoided the harm.'" *Id.* Summary judgment, therefore, was appropriate since the plaintiff could not establish proximate causation.

In *Couturier v. Bard Peripheral Vascular, Inc*., 2021 WL 2885903, at *4 (E.D. La. July 9, 2021), plaintiff brought suit against defendants, medical device manufacturers, for personal injuries, including blood clots, suffered after being implanted with an Inferior Vena Cava filter medical device manufactured by defendants. *Id.* at *1. Plaintiff asserted several claims, including state law product liability claims.

The court explained that "in a product liability case with a failure to warn claim at issue, the learned intermediary doctrine applies, and a plaintiff must prove that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician, and this failure to warn the physician was the proximate cause of the plaintiff's injuries." *Id.* Defendants argued that the learned intermediary barred plaintiff's claims because the operating physician did not "recall reading the IFU" and therefore "the content of the [Instructions for Use ("IFU")] was not the proximate cause of plaintiff's injuries." *Id.* at *8.

In response, the plaintiff argued that defendants had "multiple avenues to warn Dr. Mena—aside from the IFU—including the sales representatives visiting the hospital and the letters Bard wrote to doctors about their filters." *Id*. The plaintiff also argued that the filter device had significantly higher rates of fracture, migration, and perforation than other filters and these "non-obvious risks" of injury were not disclosed in defendants' warnings. *Id.* The plaintiff also pointed to "studies and analyses" that the defendants conducted themselves, which showed that "the risk of failure was statistically significantly higher." *Id*. Additionally, in deposition, the operating doctor "testified that had he been provided with this information, he would have gone to the hospital to get a different filter to use." *Id*.

The court denied the defendants' motion for summary judgment after finding that a manufacturer's duty to warn is "a continuing one" and that a genuine issue of material fact existed as to whether the increased rate of failure of the filter device "rendered defendants' warnings inadequate" given the deposition testimony and defendant's own studies as argued by plaintiff. *Id.*

While the court did not grant summary judgment, it did make several factual findings to support that the operating physician may have been a superseding intervening cause potentially exonerating the manufacturer from the product liability claims. Specifically, both of the parties' experts opined that the operating physician "improperly placed the filter, which increased the risk of complications." *Id.* at *10. Also, the operating physician conceded that "he did not follow the IFU in several material ways," and "did not see Plaintiff for any follow-up after the implantation and conceded he, therefore, could not have had a discussion with the Plaintiff about potential removal of the filter." *Id.* at *11.

These decisions demonstrate that—when moving for summary judgment in product liability cases based on the lack of proximate cause—the key issue often will be whether the proposed warnings would have actually altered the doctor's treatment, not whether the doctor would have passed information onto the patient or a patient's family member.

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