Products Liability Law Daily Wrap Up, DESIGN AND MANUFACTURING DEFECTS—MEDICAL DEVICES—N.D. Iowa: Mesh implant patient had no evidence supporting manufacturing defect or failure to warn claims, (Aug. 11, 2020)

Products Liability Law Daily Wrap Up

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By David Yucht, J.D.

The court sustained the patient's negligent design claim but ruled that the patient abandoned her related strict liability claims.

A federal judge in Iowa found that a vaginal mesh implant patient failed to show any evidence supporting her claim of negligence based on defective manufacturing. Consequently, the court granted the mesh manufacturer's motion for summary judgment on that claim. Additionally, because the patient failed to provide discovery from her surgeon, the court found that she could not sustain her negligent failure to warn claim. However, the court determined that enough evidence was presented on her negligent design claim to survive summary judgment. Although the patient defended her negligence claims, the court ruled that she had abandoned her strict liability claims, which were based on similar theories (*Kelly v. Ethicon , Inc.*August 7, 2020, Williams, C.).

A woman was implanted with a vaginal tape mesh to stabilize her prolapsed bladder. She alleged that, as a result of the device corroding, oxidizing, or eroding, she suffered from, among other things, depression, pelvic pain, continued and worsening incontinence, and abdominal pain. Allegedly, she did not receive any descriptive materials about the implant device before her surgery. She indicated that her doctor failed to inform her of the potential risks posed by the device. The patient asserted 17 claims against the device manufacturer, including negligence, strict liability, breach of warranties, fraud-related claims, negligent misrepresentation, negligent infliction of emotional distress, violation of consumer protection laws, gross negligence, and unjust enrichment. The manufacturer moved for summary judgment.

Negligent manufacturing and design. The court granted the manufacturer's motion for summary judgment on the patient's negligence claim to the extent it was based on negligent manufacturing. Under Iowa law, a manufacturing defect claim requires a showing that the product deviated from its intended design. The product must have some defect at the time of sale which caused the subject injuries. Here, the patient pointed to no evidence supporting her negligent manufacturing claim. She failed to present evidence of a defect and how that defect caused her injuries, and she did not specify what about the implant was allegedly defective. Her mere intent to present evidence on this claim in the future was insufficient to sustain this claim. The court found that the design defect claim, which was not challenged here by the manufacturer, was supported by the evidence.

Negligent failure to warn. The court also granted the manufacturer's motion for summary judgment on the negligent failure to warn claim. The manufacturer asserted that there was no proof that an alleged defect in the warnings proximately caused the patient's injuries. Under Iowa law, the relevant inquiry on a negligent failure to warn claim is whether a reasonable manufacturer knew or should have known of a danger in light of prevailing scientific knowledge, yet failed to provide an adequate warning as to that danger. Under the learned intermediary doctrine, a manufacturer of a medical device need not provide warnings directly to patients using its products if adequate warnings were given to the health care provider supplying the products to the patients. When a manufacturer supplies warnings to a health care provider, a patient must show that different or additional warnings were necessary and would have altered the health care provider's decision. Here, the patient failed to provide discovery from her treating physician on this issue. Consequently, there was no evidence that additional or different warnings would have changed how the treating physician advised the patient about the implant.

Although the patient indicated that she would have rejected the implant had she received such warnings, the court had no factual basis to conclude that her doctor would have either changed his decision or advised the patient differently had he, as a learned intermediary, received additional or different warnings.

Negligent misrepresentation. The court granted the motion for summary judgment on the negligent misrepresentation claim. Under Iowa law, negligent misrepresentation requires, among other things, a supplying of false information for the guidance of others which is justifiably relied upon. Here, this claim failed because there was no evidence that the patient or her physician relied on any statements of the manufacturer.

Infliction of emotional distress. The court denied the manufacturer's motion for summary judgment on the negligent infliction of emotional distress claim. Iowa law recognizes negligent infliction of emotional distress in cases where an individual has suffered emotional distress causally related to physical harm. Here, the patient sufficiently alleged physical injuries that were directly related to her emotional distress.

Other issues. The court granted the motion for summary judgment on the patient's gross negligence claim because a cause of action for gross negligence is not recognized by Iowa law. Also, the manufacturer's motion for summary judgment was unopposed and granted as to the patient's claims for breach of express warranty and violation of consumer protection laws. Interestingly, the court found that the patient abandoned her strict liability claims that were related to the negligence claims she defended. The patient's fraud-related claims all failed because she failed to show proof of justifiable reliance. Moreover, her breach of implied warranty claim was barred by Iowa's statute of limitations. Finally, the motion for summary judgment was denied as to the patient's claim of unjust enrichment.

The case is No. 20-CV-2036-CJW-MAR.

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Companies: Ethicon, Inc.; Johnson & Johnson

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