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SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CV 2017-000927
Consolidated

07/22/2019

HONORABLE ROGER E. BRODMAN

CLERK OF THE COURT
M. Corriveau
Deputy

DANNY MCMAHILL, et al.

ASHLEY CARRINGTON CROWELL

v.

C R BARD INC, et al.

KRISTINE L GALLARDO

LINCOLN COMBS
JAMES E FUCETOLA
CHRISTOPHER W JENSEN
STEPHEN I LESHNER
MARK S O'CONNOR
JOSHUA S PARILMAN
PAUL L STOLLER
TIMOTHY G TONKIN

RULING ON MOTION FOR SUMMARY JUDGMENT AND MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. ROBERT MCMEEKING

Defendants have filed a Motion for Summary Judgment and a Motion to Exclude Testimony of Dr. Robert McMeeking. The Court has considered the motions, responses and replies. The Court held oral argument on July 16, 2019.

I. RULING ON MOTION FOR SUMMARY JUDGMENT

A. Background.

This case concerns plaintiff Joseph Grossman. Plaintiff was implanted with a Bard Meridian IVC Filter on August 5, 2012, after sustaining serious injuries in an automobile accident. The filter was implanted by Dr. Lavi Nissim at a Phoenix area hospital.

On January 24, 2013, plaintiff underwent a scheduled procedure to percutaneously retrieve the filter. Before retrieving the filter, Dr. Nissim discovered one fractured strut in the IVC and another in the pulmonary artery. On February 1, 2013, the fractured strut in the IVC was removed. A fractured strut remains in plaintiff's right pulmonary artery.

The Meridian filter is a successor to Bard's Eclipse and G2 filters. The Meridian filter is electropolished and has caudal anchors designed to reduce the risk of caudal migration and tilt. The Meridian was cleared by the FDA on August 24, 2011, for retrievable use. The Meridian filter has not been manufactured since August 29, 2014.

The parties agree that Arizona law applies to all of the claims in this case.

B. Summary Judgment on the Design Defect Claim Is Denied.

1. There is a question of fact whether the Meridian filter is an unavoidably unsafe product; Restatement (Second) of Torts § 402, comment k.

In Arizona, to establish a claim for strict liability design defect or negligent design defect, a plaintiff must prove that "the product is defective and unreasonably dangerous." *Mather v. Caterpillar Tractor Corp.*, 23 Ariz. App. 409, 411 (1975) ("In both instances [strict liability and negligence] appellant had to prove that the [product] was in a defective condition and unreasonably dangerous."). To determine liability for a defectively designed product, Arizona has adopted the *Restatement (Second) of Torts,* § 402A. *O.S. Stapley Co. v. Miller*, 103 Ariz. 556 (1968). Comment k to § 402A provides that product is not defective or unreasonably dangerous if the product is "unavoidably unsafe" and "incapable of being made safe for [its] intended and ordinary use" and is accompanied by proper warnings. *Restatement (Second) of Torts* § 402A, cmt. k; *see Gaston v. Hunter*, 121 Ariz. 33, 46-47 (1978) (applying comment k to experimental prescription drug). The Court is not aware of any Arizona case applying comment k to prescription medical devices.

Defendants argue that summary judgment is appropriate because the Meridian filter, like all IVC filters, has inherent risks and is thus "unavoidably unsafe." Plaintiff disagrees and asserts

that Bard has not shown the Meridian filter is "unavoidably unsafe" as a matter of law. Plaintiff argues that the Meridian filter is not "unavoidably unsafe" because there are other IVC filters that are safer and pose less risk of fracture. Plaintiff also argues that the Meridian did not come with adequate warnings.

Plaintiff has presented evidence that the Meridian filter has a higher rate of fracture, as much as three times higher, than other available IVC filters, including filters manufactured by Bard. Thus, the Court cannot conclude that the Meridian filter is "unavoidably unsafe" as a matter of law. *See Miller v. Stryker Instruments*, 2012 WL 1718825, *19 (D. Ariz. Mar. 29, 2012) (court denied summary judgment on design defect claim reasoning that defendant had not established that product was "unreasonably unsafe" and plaintiff had produced evidence that defendant engaged in improper marketing and distribution of the device). There are questions of fact concerning whether the Meridian filter was "unreasonably unsafe" and whether the filter was "incapable of being made safe" for its intended use. There are also fact questions concerning whether Bard gave adequate warnings about the Meridian's risks, specifically the alleged increased risk of fracture.

2. <u>There is a question of fact whether reasonable healthcare providers would not prescribe the Meridian filter to any class of patients; Restatement (Third) of Torts: Products Liability, § 6(c).</u>

Defendants also argue plaintiff's design defect claims are barred by *Restatement (Third) of Torts: Products Liability*, § 6(c).

Defendants first claim that § 6(c) would be adopted in Arizona. Plaintiff does not challenge this assertion, so the Court's adoption of § 6(c) is uncontested.[1]

To establish a design defect claim involving prescription medical device, section 6(c) requires the plaintiff to show that "the foreseeable risks of harm posed by the . . . medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the . . . medical device for any class of patients." *Restatement (Third),* § 6(c).

1. Although the Arizona Supreme Court has not adopted the entirety of the *Restatement (Third) of Torts: Products Liability*, the supreme court recently adopted § 6(d) as its expression of the learned intermediary doctrine. *Watts v. Medicis Pharmaceutical Corp*., 239 Ariz. 19, 24, ¶ 14 (2016). Even without agreement of the parties, the Court believes it is likely the Arizona Supreme Court would also adopt section (c) as the statement of Arizona law for determining which medical devices are subject to design defect claims.

The Court finds that application of section 6(c) raises questions of fact that should be resolved by the jury. There is evidence the Meridian filter fractured at much higher rates than other filters on the market. Dr. Nissim testified that he was "shocked" to learn the Meridian filter had fractured and discontinued its use in his practice in favor of another filter which had a reduced risk of fracture. Evidence shows that Dr. Nissim stopped using the Meridian filter about a year after Mr. Grossman's surgery and after two of his patients experienced fractures. *See* Nissim depo. at p. 134-35. He testified that "we saw more anecdotal reports of fractures with the Meridian filter." *Id*. Such evidence creates a triable issue on whether a reasonable healthcare provider would prescribe the device for any class of patient. Bard discontinued manufacturing the Meridian in August 2014, arguably because of the high failure rate. A reasonable jury could conclude that reasonable healthcare providers, knowing of these increased risks, would not have prescribed the Meridian filter for any class of patients.

IT IS ORDERED that Bard's motion for summary judgment on the design defect claim is denied.

C. Summary Judgment on the Failure to Warn Claim Is Denied.

1. There are questions of fact on the adequacy of the warnings for the Meridian filter.

A products liability claim may be based on inadequate warnings that render a product defective and unreasonably dangerous. *Gosewisch v. American Honda Motor Co*., 153 Ariz. 400, 403 (1987). Prescription medical device manufacturers discharge their duty to warn if they give adequate warnings regarding the foreseeable risks of harm to the prescribing physician. *Watts*, 239 Ariz. at 24, ¶ 13.

Defendants argue that the warnings given for the Meridian filter were adequate as a matter of law. Specifically, the IFU warned physicians that "Filter fractures are a known complications of vena cava filters." It also warned of "serious pulmonary and cardiac complications requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques." Plaintiff contends that Bard only provided general warnings about risks associated with all IVC filters, but failed to warn prescribing physicians that the Meridian filter had a higher rate of fracture than other filters on the market, including Bard's own Eclipse filter and Simon Nitinol Filter ("SNF"). Plaintiff has presented evidence that the Meridian filter fractured at three times greater than Bard's Eclipse filter and over three and a half times greater than the SNF.

The Court cannot say that the Meridian filter warnings were adequate as a matter of law. Summary judgment is denied because there are facts from which a jury could reasonably conclude that Bard did not adequately warn of the risks specific to the Meridian filter.

2. There are questions of fact on proximate causation.

Defendants argue that the alleged inadequate warnings could not have been the proximate cause of plaintiff's injuries because Dr. Nissim testified he did not read the IFU for the Meridian. But the IFU only warned about generic risks of all IVC filters. The IFU did not contain any information about the specific increased risks of failure or fracture of the Meridian filter. As defendants point out, Dr. Nissim was aware of the general risks of IVC filters to tilt, fracture, migrate or perforate before treating plaintiff. Defendants have not demonstrated that the IFU, had he read it, would have given Dr. Nissim any information about the Meridian filter that he did not already know from his experience as a practicing radiologist.

The Court finds there is a question of fact on the issue of causation. On the evidence presented, a reasonable jury could find that had Dr. Nissim been advised about the increased risk of fracture with the Meridian filter he would not have prescribed the filter for plaintiff. Dr. Nissim is one of the radiologists as his hospital involved in selection of IVC filters. Dr. Nissim relied on Bard's sales representatives in making the decision to use Bard filters. The Meridian filter was advertised as having "enhanced fracture resistance" and was designed to "decrease the likelihood of fracture to occur." Dr. Nissim said he would have expected Bard's sales representatives to inform him if Bard was aware that the Meridian filter had higher failure rates compared to other Bard filters. Dr. Nissim testified that when he went into the procedure with plaintiff he did not consider fracture a significant risk. He testified he was "shocked" when the he learned that plaintiff's Meridian filter had fractured. Because of his adverse clinical experience with the Meridian filter in Mr. Grossman's case and others, Dr. Nissim discontinued using the filter in his practice.

IT IS ORDERED that Bard's motion for summary judgment on the failure to warn claim is denied.

D. Bard Is Entitled to Summary Judgment on the Express Warranty Claim.

Plaintiff alleges that defendants warranted that the Meridian filter had "enhanced fracture resistance" and provided "optimal security" and "safety." Plaintiff claims these statements were false and constituted a breach of express warranty.

"Under Arizona law, an express warranty claim requires a showing that the seller made an affirmation of fact or promise that became the basis of the bargain." *D'Agnese v. Novartis Pharmaceuticals Corp.,* 952 F. Supp. 2d 880, 893 (D. Ariz. 2013). Further, Arizona requires privity between the manufacturer and the injured plaintiff. *Flory v. Silvercrest Industries, Inc.*, 129 Ariz. 574, 578 (1981).

Plaintiff's express warranty claim fails because there is no evidence plaintiff received any representations about the performance of the filter before it was implanted. The claim also fails for lack of privity. Bard did not sell the Meridian filter directly to plaintiff.

IT IS ORDERED that Bard's motion for summary judgment on the breach of express warranty claim is granted.

E. Bard Is Entitled To Summary Judgment on the Punitive Damages Claim.

A.R.S. § 12-689 provides that a manufacturer or seller is not liable for exemplary or punitive damages if:

> The product alleged to have caused the harm was designed, manufactured, packaged, labeled, sold or represented in relevant and material respects according to the terms of an approval, conditional approval, clearance, license or similar determination of a government agency.

Here, undisputed evidence shows that the Meridian filter received clearance from the FDA. As a result, the statute bars plaintiff's claim for punitive damages.

Plaintiff makes several attacks on the statute. First, plaintiff argues that the statute was enacted after plaintiff's filter was implanted. The Court disagrees. Undisputed evidence shows that the filter was implanted on August 5, 2012. *See* Defendants' Exh. E (post-op report). Westlaw shows the effective date of the statute is August 2, 2012. Moreover, plaintiff's rights did not vest until he filed for litigation. *Hall v. A.N.R. Freight Sys., Inc.*, 149 Ariz. 130, 140 (1986). The statute was effective for years before plaintiff filed for litigation.

Second, plaintiff argues that the statute violates three separate provisions of the Arizona Constitution. The Court disagrees. Article 18, § 6 does not apply. That provision affects the right "to recover damages for injuries." Punitive damages are not awarded to compensate for injuries. "Punitive damages are appropriately awarded in tort cases to punish the wrongdoer and deter others from emulating the misconduct." *Hudgins v. Southwest Airlines, Co.*, 221 Ariz. 472, 486, ¶ 38 (App. 2009). "Punitive damage awards are not intended to compensate plaintiffs but exist to punish the wrongdoer and deter future harmful conduct." *Id*. at 489, ¶ 50. The provision is not an impermissible "special law," nor does it grant unconstitutional protection to a certain class of defendants. Here, the legislature has made a determination intended to encourage the development of medical devices in Arizona.

Finally, plaintiff suggests that the statute doesn't apply because "Bard knowingly violated a material and relevant reporting requirement." Response at 16:1. In essence, plaintiff alleges that Bard duped the FDA into clearing the Meridian filter. This argument fails for at least two reasons. First, the record does not support plaintiff's contention. Second, A.R.S § 12-689(B) specifically describes the process when a party alleges that misrepresentations were made to the FDA. Subsection (2) provides the statute does not apply if the manufacturer "intentionally, and in violation of applicable regulations as determined by final action of the government agency, withheld from or misrepresented to the government agency information material to the approval or maintaining of approval of the product . . . " (Emphasis added.) Of course, there is no evidence of a "final action" by the FDA indicating that Bard withheld any information. There is no evidence that the FDA withdrew the Meridian filter clearance or took final action against Bard.

Similarly, subsection (4) provides that the statute does not apply as follows:

> After the product was sold or the service provided, a government agency found that the manufacturer, service provider or seller knowingly violated applicable regulations requiring the reporting to that government agency of the risks of harm and the unreported information was material and relevant to the harm that the claimant allegedly suffered. (Emphasis added)

Once again, there is no evidence in the record that the FDA "found" that material information related to the Meridian filter was knowingly unreported, material or relevant to the harm plaintiff allegedly suffered. Nothing in the record supports claim that the FDA ever "found" that it was duped by Bard.

In conclusion, A.R.S. § 12-689 bars plaintiff's claim for punitive damages.

IT IS ORDERED that Bard's motion for summary judgment on the punitive damages claim is granted.

F. Bard Is Entitled to Summary Judgment on All Remaining Claims.

Bard moved for summary judgment on each of the remaining claims for manufacturing defect, failure to recall/retrofit, negligent misrepresentation, breach of implied warranty, fraudulent misrepresentation, and fraudulent concealment. Plaintiff did not respond to any of these arguments and has thus conceded that summary judgment should be granted on these claims.

IT IS ORDERED that Bard's motion for summary judgment is granted on the manufacturing defect claim, the failure to recall/retrofit claim, the negligent misrepresentation claim, the breach of implied warranty claim, the fraudulent misrepresentation claim, and the fraudulent concealment claim.

II. RULING ON MOTION TO EXCLUDE DR. MCMEEKING

Defendants filed a motion to preclude some portions of the expert testimony of Dr. Robert McMeeking. As an initial matter, the Court rejects defendants' argument that Dr. McMeeking's testimony should be precluded because he has not designed alternative devices or performed sufficient calculations or testing. Dr. McMeeking has expertise in the area of IVC filter design, and defendants' objections go to the weight, not admissibility, of his opinions. Similarly, the Court rejects the claim that Dr. McMeeking's opinions are unreliable because they have not been peer-reviewed. In this case such objections go to weight, not to admissibility.

Dr. McMeeking has testified in other IVC cases, and defendants have no objection to Dr. McMeeking's opinions "that are purely related to fracture." Reply at 4:25. In this case, Dr. McMeeking testified that it is more probable than not that the fracture occurred due to fatigue. Response at 4:18-19. Defendants acknowledge that Dr. McMeeking may testify that the Meridian filter is unable to withstand cyclic loading. There is no challenge to the admissibility of Dr. McMeeking's claim that the Meridian design introduces a strain concentration where the limbs merge into the tubular cap of the filter.

The Court, however, has concerns about other portions of Dr. McMeeking's testimony. Dr. McMeeking offers the opinion that the Meridian filter is defectively designed because it is subject to tilt, perforation and caudal migration. He offers a "two-tiered" design to prevent tilt and other features to prevent perforation and caudal migration. However, there is no evidence that Mr. Grossman's filter tilted, perforated the IVC or suffered inappropriate caudal migration.

In his deposition, Dr. McMeeking testified that he could not say that a two-tiered design would have prevented Mr. Grossman's complications. Depo. at 35:4-18. He could not say that a design that reduced perforation would have prevented Mr. Grossman's complications. *Id*. at 35:23-36:3. He found "no evidence" that migration contributed to the fracture. *Id*. at 36:12-18. All Dr. McMeeking could testify to is the following:

> I can't make that connection [between caudal anchor design and fracture] directly in Mr. Grossman's case, but I can say that the caudal anchors and penetration limiters would have reduced the risk he faced in general. And it is entirely possible that they would have eliminated whatever it is that happened that led to the fracture of his filter.

Id. at 37:19-25.

But the "possibility" that something may have occurred or reduced the risk is not sufficient. In an ordinary negligence case, a plaintiff must prove causation by a probability standard. *Benkendorf v. Advanced Cardiac Specialists Chartered*, 228 Ariz. 528, 530, ¶ 8 (App. 2012). "The rationale behind the requirement that a plaintiff must generally offer expert testimony about probable causation stems from the basic principle that a plaintiff has the burden of proving his or her injuries were caused by defendant's conduct." *Id.* at ¶ 9.

In *Clemons v. DMB Sports Clubs, Ltd. Partnership*, 2015 WL 8166584 (Ariz. App. Dec. 8, 2015), plaintiff alleged that he suffered a traumatic brain injury resulting from a doctor's delay in referring the plaintiff to treatment. The court of appeals held that, by itself, evidence that "the faster [a person suffering traumatic brain injury] receives treatment, the better the outcome" did not suffice to establish that the delay in treatment was a probable cause of injury. *Id.* at *3, ¶ 13. Likewise, the fact that Dr. McMeeking believes that caudal anchors and penetration limiters possibly would have reduced the risk or resulted in a better outcome does not establish that the lack of caudal anchors and penetration limiters probably caused Mr. Grossman's injury.

Since the Grossman case presents no evidence of tilting, perforation, or inappropriate caudal migration, the Court finds that Dr. McMeeking's two-tier design criticism of the Meridian filter is more unfairly prejudicial than probative under a Rule 403 balancing. Dr. McMeeking is precluded from testifying that tilt, perforation or caudal migration caused the filter to fracture. He also is precluded from testifying that the Meridian filter is defectively designed because it doesn't sufficiently account for tilt, perforation or caudal migration. All such evidence is excluded under a Rule 403 balancing. The evidence is more likely to mislead or confuse the jury than being probative to an issue in dispute in the case. *See Brethauer v. General Motors Corp.*, 221 Ariz. 192, 197, ¶ 17 (App. 2009) (evidence of an earlier truck recall was inadmissible because the probative value was outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury).

Evidence may be inadmissible for one purpose but nevertheless admissible for another. Plaintiff argues that Dr. McMeeking's testimony may be relevant for other purposes, such as to rebut Bard's claim that the benefits of the Meridian filter exceed the risks. The Court cannot address this argument in the abstract. Whether such testimony becomes relevant is an issue to be determined as the evidence is presented.

IT IS ORDERED that Bard's motion is granted in part and denied in part. Bard acknowledges that Dr. McMeeking is qualified to testify that the Meridian filter is defectively designed due to metal fatigue arising from its inability to withstand cyclical loading. The motion is granted to the extent that Dr. McMeeking is precluded from testifying that the Meridian filter

was defectively designed because it was susceptible to tilt, perforation and caudal migration and, without court approval, plaintiff shall not introduce evidence of Dr. McMeeking's design changes (such as the two-tier system) that addresses these issues. In the event plaintiff believes that the excluded evidence is admissible for another purpose, plaintiff may urge the Court to reconsider this ruling outside the presence of the jury.