UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
AT LEXINGTON

VIRGINIA STURGEON, **Plaintiff,** **V.** **JOHNSON & JOHNSON and SYNTHES, f/k/a Synthes, Inc. n/k/a Syth, Inc.** **Defendants.**	**CIVIL ACTION NO. 5:15-93-KKC** **OPINION AND ORDER**

*** *** ***

This matter is before the Court on the defendants (DE 65) motion for summary judgment. For the following reasons, the motion will be granted.

I. Background

The plaintiff, who is acting *pro se*, fractured her wrist and, as part of the treatment, Dr. Andrew Ryan implanted a plate into or on her wrist. She alleges that the plate was defective and she has suffered physical, financial, and emotional damages. She asserts claims against defendant Synthes, which she alleges manufactured the plate, and against defendant Johnson & Johnson, which she asserts wholly owns Synthes.

There is very little dispute about any of the material facts of this matter.

In her complaint, the plaintiff alleges that, after Dr. Ryan inserted the plate, she began to experience excruciating pain and that Dr. Ryan performed imaging studies and told her the plate was "bent." Weeks later, she again began experiencing pain and Dr. Ryan performed additional imaging studies and informed her that the plate was now broken into two pieces. Dr. Ryan then removed the two pieces and replaced them with an identical plate manufactured by Synthes.

In her complaint, plaintiff asserts that the plate was defective and unreasonably dangerous and unsafe for its intended purpose because of a defect in its design and manufacture, and assembly. She also asserts that the defendants – who the Court will refer to collectively as Synthes –failed to provide adequate warning of the plate's dangers. She further asserts that Synthes impliedly warranted that the plate was safe for its intended purpose of joining broken bones and that it breached that warranty.

Under Kentucky law, "[a] party injured by a product can bring suit for that injury under three different theories: (1) breach of warranty under the Uniform Commercial Code, (2) negligence, or (3) strict liability in tort." *Ostendorf v. Clark Equip. Co.*, 122 S.W.3d 530, 535 (Ky. 2003) (citing *Williams v. Fulmer*, *Ky.*, 695 S.W.2d 411 (1985)). Sturgeon states in her response brief that she asserts a claim under each of these theories and for failure to warn. (DE 67, Response at 2.) Synthes moves for summary judgment on all claims.

II. Analysis

A. Breach of warranty

As to Sturgeon's breach-of-warranty claim, "Under Kentucky law, privity of contract is an essential element of a claim for breach of warranty." *Allen v. Abbott Labs.*, No. CIV.A. 11-146-DLB, 2012 WL 10508, at *5 (E.D. Ky. Jan. 3, 2012) (citing *Compex Int'l Co. v. Taylor,* 209 S.W.3d 462 (Ky.2006)). "Privity of contract requires 'an underlying contractual relationship,' one existing in a 'buyer-seller relationship.'" *Id.* (quoting *Compex*, 209 S.W.3d at 465.)

"If liability is based on sale of the product, it can be extended beyond those persons in privity of contract only by some provision of the U.C.C. as adopted in Kentucky." *Williams v. Fulmer*, 695 S.W.2d 411, 413 (Ky. 1985). Kentucky's statutes provide that the warranty of a seller "extends to any natural person who is in the family or household of [the seller's]

buyer or who is a guest in his home if it is reasonable to expect that such person may use, consume or be affected by the goods and who is injured in person by breach of the warranty." K.R.S. § 355.2–318. "Thus, privity of contract for purposes of a breach of warranty claim requires a buyer-seller relationship, with narrow statutory exceptions provided for the family members and household guests of that buyer." *Abbott Labs*., 2012 WL 10508, at *5. Synthes did not sell the plate to Sturgeon. It sold the plate to Central Baptist Hospital. Accordingly, Sturgeon's claim for breach of warranty must be dismissed.

B. Strict liability and negligence

For Sturgeon's claim that Synthes defectively designed the plate, under either a strict liability or negligence theory, she must show that Synthes failed to "use reasonable care to protect against foreseeable dangers." *Ostendorf*, 122 S.W.3d at 535. "[T]he trier of fact must employ a risk-utility balancing test that considers alternative safer designs and the accompanying risk pared against the risk and utility of the design chosen to determine whether the manufacturer exercised reasonable care in making the design choices it made." *Id*. (quoting *Gregory v. Cincinnati Inc*., 538 N.W.2d 325, 329-30 (Mi. 1995)) (intern ellipsis and quotations omitted). This means the plaintiff must produce proof of "a feasible alternative design." *Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35, 42 (Ky. 2004), as amended (June 14, 2004).

"[E]xpert testimony is almost always required to meet this burden." *Thomas v. Manchester Tank & Equip. Corp.*, No. CIV.A. 3:03CV-705-H, 2005 WL 3673118, at *1 (W.D. Ky. May 13, 2005). "As a general rule, expert witnesses are generally necessary, indeed essential, in products liability cases, as they are in medical malpractice actions, to prove such matters as a product defect and proximate causation, unless of course the nature of the defect and resultant injuries are so obvious as to fall within the general knowledge of

the ordinary person." *Thomas*, 2005 WL 3673118, at *1 (quoting William S. Haynes, Kentucky Jurisprudence: Torts § 21-18 (1987)).

Here, Sturgeon has presented no expert evidence or other competent evidence that, in designing the plate, Synthes failed to use reasonable care to protect against foreseeable dangers. Nor has she submitted proof of a feasible alternative design. She submits an article titled "Premature Failure in Orthopedic Implants: Analysis of Three Different Cases." This article is not authenticated and does not address the plate at issue in this case. Sturgeon disclosed only one expert witness: metallurgist John Jendrzejewski, Ph.D. Dr. Jendrzejewski testified in his deposition that he did not have the information or expertise to determine whether there is a design defect in the plate. (DE 65-11, Jendrzejewski Dep. at 86.)

The nature of any defect in the plate is not something that falls within the general knowledge of ordinary people. Without expert testimony on any defect in the design of the plate, the jury would be left to speculate as to whether the plate broke or bent because of a defective design. Accordingly, Sturgeon's strict liability and negligence claims based on any design defect in the plate must be dismissed.

As to Sturgeon's strict liability and negligence claims based on a manufacturing defect, this requires evidence that, in manufacturing the product, Synthes somehow deviated from the product's design in a way that created an unreasonable risk of harm. *Wright v. Gen. Elec. Co*., 242 S.W.3d 674, 682 (Ky. Ct. App. 2007). Sturgeon has pointed to no such proof – expert or otherwise. Her only expert, Dr. Jendrzejewski, testified that, because he had not seen the design drawings, he had no way of knowing whether the plate was manufactured according to specifications. DE 65-11, Jendrzejewski Dep. at 86.)

In her response brief, Sturgeon states that she "believes plate failed due to manufacturing errors or design flaws." (DE 67, Response at 3.) Sturgeon's "beliefs," however, are not sufficient to withstand summary judgment. She also points to certain statements by Dr. Ryan and states that they "confirm that he also felt the plate might be defective." (DE 67, Response at 3.) Even if Dr. Ryan's testimony were to be interpreted in this manner, his feelings that the plate "might" have been defective are also insufficient to prevent summary judgment.

Sturgeon argues that Synthes has offered no expert "to definitively prove that internal cracks *did not* cause the failure of the implant." (DE 67, Reponse at 7 (emphasis added.)) However, Sturgeon is the plaintiff in this case. When faced with a motion for summary judgment, she cannot simply rest on the allegations in her complaint. Instead, she must present adequate proof supporting those allegations. If she fails to do so, the defendant does not need to disprove her case to prevail on its motion for summary judgment. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986) ("[W]e find no express or implied requirement in Rule 56 that the moving party support its motion with affidavits or other similar materials *negating* the opponent's claim.")

Accordingly, Sturgeon's strict liability and negligence claims based on any manufacturing defect must also be dismissed.

C. Failure to warn

As to Sturgeon's claim that Synthes failed to warn her that the plate may break, Kentucky has adopted the "learned intermediary doctrine." *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 770 (Ky. 2004). This doctrine provides "an exception to the general rule that a manufacturer's duty to warn of any risks or dangers inherent in the product runs to the ultimate consumer." *Id.* at 762. Under that doctrine, the duty to warn of the foreseeable

risks of harm of a medical device is satisfied if adequate warnings are given to the patient's health care provider. *Id.* (citing Restatement (Third) of Torts: Prod. Liab. § 6 (1998)).

Synthes sold the plate to Central Baptist Hospital. There is no dispute that the packaging for the plate included an insert that contained warnings to the operating surgeon about the potential that the plate may break "[i]f there is a delayed union or nonunion of bone." (DE 67, Response at 2.) The packaging insert contained extensive warnings, including the following:

- All metallic surgical implants are subject to repeated stresses in use. . . which can result in metal fatigue.
- It is important to note that these implants may break at any time if they are subject to sufficient stresses.
- The patient must be warned that noncompliance with postoperative instructions could lead to loosening or breakage of the implant, and/or possibly migration, requiring revisional surgery.
- Metallic internal fixation devices cannot withstand activity levels and/or loads equal to those placed on normal healthy bones as these devices are not designed to withstand the unsupported stress of full weight-bearing or load-bearing.
- These devices can break when subjected to the increased loading associated with delayed union or nonunion.
- The patient must be made aware of the limitations of the implant and that physical activity and full weight-bearing or load-bearing have been implicated in premature loosening, bending or fracture of internal fixation devices.

Sturgeon does not allege that those warnings were inadequate. Accordingly, her failure to warn claim must be dismissed.

III. Conclusion

For all these reasons, the Court hereby ORDERS as follows:

1) the defendant's motion for summary judgment (DE 65) is GRANTED;

2) all of the plaintiff's claims against the defendants are DISMISSED;

3) this action is DISMISSED and STRICKEN from the Court's active docket; and

4) the Court will enter a judgment consistent with this opinion.

Dated September 14, 2017.

KAREN K. CALDWELL, CHIEF JUDGE
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY