IN THE UNITED STATES DISTRICT COURT FOR THE

WESTERN DISTRICT OF OKLAHOMA

HENRY C. NOLL and MARILYN NOLL,	)	
	)	
Plaintiffs,	)	
vs.	)	NO. CIV-08-1379-D
	)	
APEX SURGICAL, LLC n/k/a OMNI LIFE SCIENCE, INC.,	)	
	)	
	)	
Defendant.	)	

O R D E R

Before the Court are the Plaintiffs' Motion for Partial Summary Judgment [Doc. No. 35].[1] The parties have submitted multiple briefs accompanied by a voluminous record.

I. Background:

In this action, Plaintiffs assert claims based on alleged defects in an artificial hip replacement device implanted in Plaintiff Henry Noll's ("Noll") right hip in 2003. The hip replacement device ("Device") was manufactured, marketed and sold by Defendant. Plaintiffs contend that, in 2008, the Device failed, resulting in the need for replacement surgery. Plaintiffs assert claims of negligence, gross negligence, strict product liability, breach of warranty, misrepresentation and /or fraudulent concealment, and loss of consortium; they seek both actual and punitive damages.

Plaintiffs' motion seeks judgment only on their claims of strict product liability and punitive damages. According to Plaintiffs, the undisputed material facts establish that the Device was defective and dangerous when it left Defendant's possession and control, that Defendant knew of the defect, and that it failed to take corrective remedial action or warn consumers. Plaintiffs

[1]Defendant has also filed a motion for partial summary judgment [Doc. No. 34]. That motion will be addressed in a separate order.

contend the undisputed facts show that the defective Device caused Noll severe injury, and they seek a ruling that they are entitled to recover punitive damages. Defendant denies Plaintiffs' allegations and argues that, as a matter of law, the undisputed material facts establish Plaintiffs cannot recover punitive damages. Defendant also contends the record reflects that material factual disputes preclude summary judgment on Plaintiffs' strict product liability claim.

II. Summary judgment standards:

Summary judgment is proper where the undisputed material facts establish that a party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c)*; Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A material fact is one which may affect the outcome of the suit under the governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). To dispute a material fact, a plaintiff must offer more than a "mere scintilla" of evidence; the evidence must be such that "a reasonable jury could return a verdict" for him. *Id.* The facts and reasonable inferences therefrom must be viewed in the light most favorable to the non-moving party. *MacKenzie v. City & County of Denver*, 414 F. 3d 1266, 1273 (10th Cir. 2005).

If the undisputed facts establish that a plaintiff cannot prove an essential element of a cause of action, the defendant is entitled to judgment on that cause of action. *Celotex*, 477 U.S. at 322. However, a defendant need not disprove the plaintiff's claim; it must only point to "a lack of evidence" on an essential element of that claim. *Adler v. Wal-Mart Stores, Inc.*, 144 F. 3d 664, 671 (10th Cir. 1998). The burden then shifts to the plaintiff to go beyond the pleadings and present facts, admissible in evidence, from which a rational trier of fact could find for her; conclusory arguments are insufficient, as the facts must be supported by affidavits, deposition transcripts, or specific exhibits incorporated therein. 144 F. 3d at 671-72.

III. The record before the Court:

Plaintiffs' statement of facts and Defendant's response thereto reflect that numerous facts are disputed. However, the record reflects no dispute regarding several matters which are pertinent to the parties' respective arguments.

It is not disputed that the Device in question was implanted in Noll's right hip on February 24, 2003 and that the surgery was performed by Dr. Thomas Tkach ("Dr. Tkach") in Oklahoma City. At the time of the surgery, Noll was employed as a realtor in Ponca City, Oklahoma. The parties agree that, following the 2003 implant, Noll resumed normal day-to-day activities and returned to his employment. However, in June of 2008, approximately five and one-half years after his surgery, the Device implanted in Noll's hip failed[2]. On June 19, 2008, he had surgery to implant a new device.

It is also not disputed that the Device was manufactured by Defendant Apex Surgical, LLC[3], a company which was established in 1999 and began marketing hip replacement devices shortly thereafter. The record reflects that, prior to distributing the Device, Defendant obtained the necessary approval from the Food and Drug Administration ("FDA"). Prior to submitting the Device to the FDA for approval, Defendant presented it for testing and analysis by an independent laboratory; these tests were conducted by Dr. Seth Greenwald ("Dr. Greenwald") of the Orthopaedic Research Laboratories at Mt. Sinai Medical Center in Cleveland. Defendant had also conducted

[2]The parties do not dispute that the Device failed; however, the reasons for that failure are the subject of a material factual dispute.

[3]The record also reflects that Apex Surgical, LLC was acquired by Omni Life Sciences, Inc. in 2005.

its own testing and analyses of the Device.[4]

The record establishes that the package insert for the Device contained warnings and contraindications for its use in certain individuals. A copy of the insert is submitted as Attachment B to Exhibit 1 to Defendant's response brief. Among the contraindication is use in obese patients and those involved in high levels of physical activity.

It is not disputed that, on February 24, 2004, approximately one year after Plaintiff Noll's Device was implanted, Defendant received the first report of an alleged failure in the Device; the failure resulted from trauma sustained in a fall. Three additional failures were reported in 2004. The second was received on May 28, 2004, and it involved a 365-pound patient; the third failure report was received on June 2, 2004, and it involved a 250-pound patient; the fourth failure resulted when the patient jumped from a horse. Cheal Affidavit, ¶ 11; ¶14, n.1.

The record reflects that, less than three weeks after receipt of the second report of failure, Defendant sent written notifications to the implanting surgeons and the distributors; Defendant also submits evidence that it telephone each implanting surgeon to notify them of the failures, and it advised them to use their own judgment to determine if the Device was appropriate for specific patients. *Id.* ¶ 12. Defendant also began re-evaluating the torsional strength of the Device, and it developed a reinforced design. After obtaining FDA approval for its changes, Defendant began marketing the redesigned device, described as the "second-generation" device, in September of 2004. Cheal Affidavit, ¶ 14. Defendant has not manufactured the original or "first-generation" Device since July of 2004, and the last "first-generation" Device was implanted on November 9,

[4]Plaintiffs do not dispute that these tests and analyses were performed; they contend that, notwithstanding these tests, the Device was defective. Defendants, of course, argue that the record supports their contention that the Device was properly tested and distributed only after it was determined to be effective and fit for the purpose for which it was intended.

2004. *Id.* Plaintiffs appear to contend that additional failures were known to Defendant; however, they do not present undisputed evidence of any reported failure prior to Plaintiff Noll's February 24, 2003 implant.

The extensive record before the Court includes deposition testimony as well as documentation of product failure reports and numerous documents produced by Defendant which reflect internal reviews and analyses of the Device and its component parts. The parties interpret these documents differently, and their resulting arguments reflect that there are numerous factual disputes in this case. To determine the merits of Plaintiffs' motion for summary judgment, the Court has focused on those facts which are directly pertinent to their contentions.

IV. Application:

A. Strict product liability claim:

To prevail on their claim based on strict product liability or design defect, Plaintiffs must establish 1) the product was defective; 2) the product was dangerous to an extent not contemplated by an ordinary consumer; 3) the defect existed when it left the possession and control of the manufacturer; and 4) the defect proximately caused Plaintiffs' injuries. *Ahrens v. Food Motor Co.*, 340 F. 3d 1142, 1145 (10th Cir. 2003) (citing *Woods v. Fruehauf Trailer Corp.*, 765 P. 2d 770, 773-74 (Okla. 1988) and *Lamke v. Futorian Corp.*, 709 P. 2d 684, 686 (Okla. 1985)).

To prove the Device is defective, Plaintiffs must show that "it is not reasonably fit for the ordinary purposes for which such products are intended or may reasonably be expected to be used." *See* Oklahoma Uniform Jury Instruction No. 12.2 (citing *Mayberry v. Akron Rubber Mach. Corp.*, 483 F. Supp. 407, 412 (N. D. Okla. 1979)). Plaintiffs must also prove that the Device was defective at the time it left Defendant's possession and control.

Plaintiffs seek summary judgment on this claim, arguing that the evidence establishes Defendant knew the Device was defective when it was placed on the market. This contention is based on the assertion that there was a design defect because the Device had insufficient torsional strength and an inadequate pin diameter; Plaintiffs contend that Defendant was aware of these defects and distributed the device despite the knowledge of these deficiencies.

Plaintiffs support this argument by submitting Exhibit 1, an October 2006 poster exhibit which acknowledges the existence of "fatigue failure" in femoral components, and discusses improvements made in Defendant's devices in an effort to minimize or eliminate such failures. Although this 2006 poster exhibit was not developed until more than six years after Defendant's device was first distributed and more than two years after Noll's device failed, Plaintiffs maintain that this evidences Defendant's knowledge of a defect at the time it distributed its devices. As Defendants point out, however, the content of Plaintiffs' Exhibit 1 does not do so; in fact, it points to information which was developed after its initial design and distribution of the devices, including the Device at issue in this lawsuit.

Plaintiffs also rely on Defendant's internal "Design Review Minutes," which reflect a September 22, 1999 review of the device which was being designed at that time. *See* Plaintiffs' Exhibit 2. According to Plaintiffs, the minutes establish that Defendant knew when it designed the Device that its pin design was inadequate. Plaintiffs also rely on a January 24, 2000 "Risk Analysis" produced by Defendant and submitted as Plaintiffs' Exhibit 3. The Risk Analysis lists a series of "potential failure mode" items which Defendant had determined could cause problems in the Device. However, as Defendant points out, this document also shows that, with respect to each potential failure mode, the Risk Analysis lists the actions to be taken to determine what testing should be

performed to evaluate the risk, the followup to be performed, and the action to be taken to minimize or avoid the identified risk. Plaintiff's Exhibit 3.

Defendant argues Exhibit 3 also reflects that the potential failure related to inadequate pin diameter was the subject of further analysis and, in fact, resulted in Defendant's increasing the diameter prior to placing the device on the market. Furthermore, Defendant submits evidence to argue that, once the pin diameter was increased, the Device was subjected to independent testing by Dr. Greenwald's laboratory; such testing resulted in a determination that the pin diameter was adequate to support more than the established torsional loads generated by hip replacement patients, as determined by the scientific and medical community; and Dr. Greenwald recommended no further action. Affidavit of Dr. Edward Cheal,¶¶ 6-9, submitted as Defendant's Exhibit 1 in response to Plaintiffs' motion ("Cheal Affidavit"). Defendant submits evidence to support is contention that the torsional strength and resistance test performed by Dr. Greenwald actually reflected that the Device's torsional strength exceeded the existing FDA requirements as well as all known safety levels recognized at the time. Cheal Affidavit, ¶9.

Defendant contends that, contrary to Plaintiffs' assertion, the Risk Analysis submitted as Plaintiff's Exhibit 3 supports Defendant's contention that it carefully analyzed the approximately 20 potential design problems in the Device and took corrective action prior to the initial distribution of the Device. As Defendant points out, this conclusion was reached by the Honorable Joe Heaton in another case alleging Defendant's Device was defective. In *Shelton v. Apex Surgical, LLC,* Case No. CIV-08-1087-HE, Judge Heaton denied the plaintiff's summary judgment motion on the claim of strict product liability; in that case, the plaintiff relied on the same Risk Analysis presented as Exhibit 3 by Plaintiffs in this case, and she argued the Risk Analysis established that Defendant

knew the defect in the Device existed at the time it was placed on the market. Judge Heaton rejected that contention, noting:

> The document shows nothing of the kind. The document lists 20 or so features of the device which could potentially fail and identifies the testing and followup done as to each of them. If anything, it is evidence of due diligence on the part of the company in assessing the risks of the device before manufacturing it.

Order of November 13, 2009 [Doc. No. 90], Case No CIV-08-1087-HE (emphasis in original).

The Court agrees with Judge Heaton's vew of the Risk Analysis, and also concludes that it does not support Plaintiffs' contention.[5] Defendant, in fact, argues that the Device, at the time it was placed on the market, represented a state of the art device satisfying or exceeding all known pin and torsional strength requirements.[6]

Plaintiffs also repeatedly argue that Defendant's corporate representatives admitted in their depositions that Defendant knew of the design defect when the Device was placed on the market. Defendant points out in response, however, that Plaintiffs rely on isolated statements taken out of context in depositions which do not contain the purported express admissions relied upon by Plaintiffs. The Court agrees.

Having reviewed the parties' arguments and the extensive record, the Court concludes that whether Plaintiffs can prevail on their claim of strict product liability cannot be determined at the summary judgment stage. Numerous disputed material facts preclude summary judgment on this

[5]Defendant asks the Court to hold that Judge Heaton's ruling constitutes *res judicata* on this issue, and bars Plaintiffs from relitigating the claim that they are entitled to judgment on the issue of strict product liability and punitive damages. The Court declines to do so, and has instead based its ruling on the applicable law as applied to the facts in the record in this case.

[6]Defendant submits evidence to show that the Device's strength requirements actually exceeded by approximately three times the amount which was the accepted standard in the scientific and medical community at the time; it contends that later studies reflected that the 1999 and 2000 established torsional strength requirements were subsequently determined to be too low.

claim. Accordingly, Plaintiffs' motion for summary judgment on their strict product liability claim is DENIED.

B. Punitive damages:

The Oklahoma statutes authorize recovery of punitive damages under certain circumstances, including a case in which a "jury finds by clear and convincing evidence that...defendant has been guilty of reckless disregard for the rights of others." Okla. Stat. tit. 23 § 9.1.[7] In this case, Plaintiffs contend that the evidence establishes Defendant is liable for punitive damages because it knew of the defect at the time it placed the Device on the market and because, after learning of Device failures, it failed to take corrective action to notify consumers of the potential dangers of the Device.

To support their claim that Defendant knew of the defect prior to placing the Device on the market, Plaintiffs rely on the same Risk Analysis, submitted as Exhibit 3, which they offered to support their strict product liability claim. As discussed above, that document does not show that Defendants knew the Device was defective at the time it was placed on the market. On the contrary, it shows that Defendant examined the Device and analyzed the *potential* failures that might occur; further, contrary to Plaintiffs' interpretation, it shows that, with respect to each, Defendant took action to eliminate the potential for failure. Each recognized risk was identified, the action to be taken was noted, and the results of that action were noted. Plaintiffs' Exhibit 3. As Judge Heaton pointed out in rejecting the same argument in *Shelton*, the Risk Analysis does not support a claim for punitive damages; if anything, it is evidence of due diligence on the part of Defendant in assessing the risk of the device before manufacturing it.

[7]Although the statute also permits punitive damages in situations in which a defendant acted intentionally or maliciously, Plaintiffs do not rely on such circumstances in this case; they argue only that Defendant acted with reckless disregard for the rights of others.

As is also discussed above, Plaintiffs' contention that Defendant's own corporate representatives testified in depositions that they knew of the defect is simply not supported by the record. Defendant has repeatedly denied this contention, and Plaintiffs' reliance on isolated portions of testimony out of context is not persuasive.

Plaintiffs also contend that punitive damages are recoverable as a matter of law because, after Defendant received reports of failures in the Device, it continued to market the Device and failed to warn physicians and consumers of the alleged defect. The evidence reflects that, from February of 2004 through November 2, 2004, there were four reported failures of the Device. It is not disputed, however, that the first failure resulted from trauma caused by a fall, and the second involved a 365-pound individual. The undisputed evidence shows that the original product insert stated the Device was contraindicated for use by obese individuals. *See* product insert, Attachment B to Defendant's Exhibit 1 in response to summary judgment. The third failure involved a patient who weighed 250 pounds, and the fourth failure involved an individual who had jumped from a horse. Cheal Affidavit, Defendant's Exhibit 1. It is also not disputed that, within two weeks of receiving a report of the third failure, Defendant sent letters to customers, surgeons, and distributors advising them of a potential problem. Additionally, it telephoned the implanting surgeons to advise them of the potential problem and suggested they use their own judgment to determine if the Device was appropriate for their patients. Ultimately, Apex developed a "second-generation" device with increased torsional loads. The "first-generation" device was discontinued in November of 2004.

The evidence establishes that all four failures of the Device occurred more than one year after Plaintiff Noll's Device was implanted on February 24, 2003. Plaintiffs offer no evidence that Defendant was aware of any alleged failure occurring prior to that time; in fact, as noted, the first

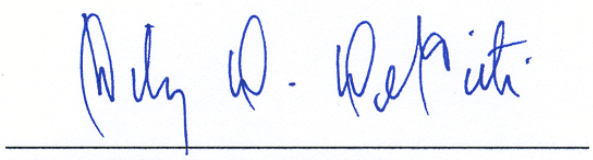
failure was not reported until February of 2004. Therefore, it cannot be disputed that Defendant was not aware of any reported failure or defect prior to Plaintiff Noll's implant.

The Court has examined the record and concludes that Plaintiffs have failed to show that they are entitled to punitive damages as a matter of law. Plaintiffs' motion for summary judgment is thus DENIED as to their claim for punitive damages. Defendant's contention that punitive damages are not recoverable as a matter of law will be addressed in the Court's separate order ruling on Defendant's motion for partial summary judgment.

V. Conclusion:

For the foregoing reasons, Plaintiffs' motion for partial summary judgment [Doc. No. 35] is DENIED.

IT IS SO ORDERED this 14th day of July, 2010.



TIMOTHY D. DEGIUSTI
UNITED STATES DISTRICT JUDGE