

**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.	)	

**ORDER**

Before the Court is the Defendant’s Motion for Partial Summary Judgment [Doc. No. 34].<sup>1</sup> Plaintiffs have timely responded, and Defendant filed a reply. In addition, Plaintiffs filed a supplemental brief, to which Defendant has responded. The parties have also submitted an extensive record.

**I. Background:**

Plaintiffs brought this action to recover damages resulting from injuries caused by 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.

Defendant seeks judgment on Plaintiffs’ breach of warranty and misrepresentation causes

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<sup>1</sup>Plaintiffs also filed a motion for partial summary judgment [Doc. No. 35]. That motion was addressed in a separate order.

of action; it also seeks judgment on Plaintiffs' damages based on lost wages or profits and on future medical expenses, as well as their punitive damages 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 (10<sup>th</sup> 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 (10<sup>th</sup> 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. The voluminous record contains numerous documents, deposition excerpts and

affidavits, and the parties' arguments reflect that many of these are subject to varying interpretations. However, the record reflects no dispute regarding several matters which are pertinent to Defendant's motion, and the Court will focus on those portions of the record which are pertinent to the issues raised by Defendant's motion.

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<sup>2</sup>. 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<sup>3</sup>, 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

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<sup>2</sup>The parties do not dispute that the Device failed; however, the reasons for that failure are the subject of a material factual dispute.

<sup>3</sup>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.<sup>4</sup>

Plaintiff Noll contends that, prior to his 2003 surgery, Dr. Tkach told him the hip replacement device would last 25 years. Although Dr. Tkach provided consulting services to Defendant in connection with its development of the Device, he receives no royalties for implanting Defendant's devices. At the time Dr. Tkach performed Noll's original implant surgery, Noll did not know Dr. Tkach had any connection to Defendant, nor did he know the identity of the manufacturer.

Noll has worked as a real estate agent in Ponca City since 1974, and he returned to his position after his February 2004 implant; he was working in that capacity when his implant failed in 2008. The record reflects that Noll's average annual income from real estate was \$16, 577.12 during the 2002-2009 time period. In 2008, his income was \$15,885, or \$692.12 less than his average for the previous six years. In 2009, after his second surgery, he earned \$2,005.88 more than the average for 2002-2008. He has been working full-time since November of 2008. According to his deposition testimony, he is able to perform all tasks necessary to listing or selling real property.

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

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<sup>4</sup>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.

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, 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.

#### IV. Application:

##### A. Breach of warranty claim:

Plaintiffs’ breach of warranty claim is based on Dr. Tkach’s alleged statement to Noll, prior to the February 24, 2003 implant surgery, that the Device would last 25 years. Defendant contends that, even if that statement was made and constituted a warranty regarding the Device, the statute of limitations on a breach of warranty claim expired prior to the filing of this lawsuit.

The parties agree that the implant of the Device constituted a sale of goods and that the Uniform Commercial Code (“UCC”) provides the applicable statute of limitations. Oklahoma’s UCC statute contains a limitations provision governing actions involving the sale of goods, including warranty claims related to such actions. The Oklahoma statute provides in pertinent part:

(1) An action for breach of any contract of sale must be commenced within five (5) years after the cause of action has accrued...

(2) A cause of action accrues when the breach occurs, regardless of the aggrieved party’s lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered.

Okla. Stat. tit. 12A § 2-725. In this case, the parties agree that the “sale” occurred when Noll’s Device was implanted on February 24, 2003. Because this lawsuit was not filed until December 23, 2008, Defendant contends the warranty claim is barred. Defendant also argues that there is no evidence it made any promise to Plaintiff Noll; in fact, there is no evidence that Defendant had any direct communication with him prior to the surgery, and he admits he did not know the identity of the Device manufacturer at that time.

In response to the statute of limitations argument, Plaintiffs argue that Dr. Tkach’s statement constituted a warranty which extended to *future* performance of the Device; accordingly, they contend their cause did not accrue at the time of the sale. As the statute provides, where future performance is at issue, the cause of action does not accrue until the breach “is or should have been discovered.” Okla. Stat. tit. 12A § 2-725 (2). Plaintiffs expressly state that the only warranty on which they rely is an alleged warranty of *future* performance. The Court concludes that those

claims are not time-barred,<sup>5</sup> and Defendant's motion is DENIED as to this contention.

Defendant also argues, however, that it cannot be liable for breach of a warranty based on Dr. Tkach's alleged promise regarding the Device's future performance because he was not employed by Defendant or speaking on its behalf when he made the statement on which Plaintiffs rely. In response, Plaintiffs contend Dr. Tkach was acting as an agent of Defendant and that his statements should be imputed to it.

An agency relationship exists "if two parties agree that one is to act for the other, or the conduct of the parties is such that it demonstrates the willingness of one to act for the other." *Haworth v. Central National Bank of Oklahoma City*, 769 P. 2d 740, 743 (Okla. 1989). "The existence of an agency relationship based on actual authority can arise by express authorization or by implied authorization." *Bayless v. Christie, Manson & Woods International, Inc.*, 2 F. 3d 347, 352 n. 6 (10<sup>th</sup> Cir. 1993).

The evidence in the record establishes it is not disputed that Dr. Tkach provided consulting services to Defendant in connection with the development of the Device. In its motion, Defendant states that Dr. Tkach is "a member of Apex Surgical, LLC." Defendant's brief at p. 6. Defendant also agrees that Dr. Tkach assisted in the design of the Device. Defendant's reply brief, pp. 9-10. Plaintiffs also submit evidence that Dr. Tkach was a member of the "design team" which developed the Device and serves as a consultant for Defendant. Deposition of Dr. Edward Cheal, Plaintiffs' response Exhibit 2, pp. 42-43. He also received compensation from Defendant as a consultant, and Plaintiffs present evidence showing he also received other forms of compensation because of his

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<sup>5</sup>In the Complaint, Plaintiffs do not rely on any statutory basis for the breach of warranty claim; in response to the motion, they argue that the only warranty on which they rely is based on Dr. Tkach's alleged statements regarding future performance of the Device. Accordingly, the Court need not consider other forms of warranty actions which could be barred by the UCC statute of limitations.

relationship with Defendant. Deposition of David LaSalle, Plaintiffs' response Exhibit 12, pp. 35-36.

Defendant argues that, because he is a physician, Dr. Tkach could not be an agent of Defendant in connection with his treatment of Plaintiff Noll. However, the authorities on which Defendant relies do not involve circumstances in which the physician had direct involvement with the device or product which is the subject of a breach of warranty claim. Whether Dr. Tkach made the statement to Noll and, if so, whether he was acting as Defendant's agent at the time are factual issues which are disputed by the parties.

The Court concludes that Plaintiffs have submitted sufficient evidence to create a material fact dispute regarding their breach of warranty claim. Accordingly, summary judgment on that claim is DENIED.

B. Misrepresentation claim:

Plaintiffs also assert a claim based on an alleged misrepresentation by Defendant regarding the Device; their claim is based on Dr. Tkach's alleged statement to Noll that the Device would last 25 years. Plaintiffs contend this representation was false or made recklessly, and Noll relied on it in agreeing to the implant surgery.

In its motion seeking judgment on this claim, Defendant asserts the contention that any representation made by Dr. Tkach cannot be attributed to Defendant. Plaintiffs again argue that Dr. Tkach was acting as Defendant's agent when he made the statement. As noted herein in connection with the breach of warranty claim, the record establishes that material factual disputes preclude a conclusion regarding the existence of an agency relationship between Defendant and Dr. Tkach. Accordingly, this claim cannot properly be adjudicated in a motion for summary judgment, and



Defendant's motion as to this claim is DENIED.

C. Damages :

Defendant also seeks summary judgment on the issue of several categories of damages which Plaintiffs seek to recover, arguing that the undisputed material facts establish Plaintiffs cannot recover damages for lost wages or future medical expenses. Defendant also seeks judgment on their claim for recovery of punitive damages.

1. Lost wages/profits:

Plaintiffs seek the recovery of damages based on their contention that, as a result of the second hip replacement surgery, Noll's income from his work as a real estate agent will be diminished. Defendant seeks judgment on this aspect of Plaintiffs' damages claim, arguing that the evidence on which it is based is too speculative to permit recovery under Oklahoma law.

Although Oklahoma permits recovery of damages based on lost profits or income, the loss must be "capable of reasonably accurate measurement or estimate." *Digital Design Group, Inc. v. Information Builders, Inc.*, 24 P. 3d 834, 844 (Okla. 2001). "Oklahoma law prohibits recovery of damages that are uncertain and speculative." *Weyerhaeuser Co. v. Brantley*, 510 F. 3d 1256, 1267 (10<sup>th</sup> Cir. 2007) (citing *Great Western Motor Lines, Inc. v. Cozard*, 417 P.2d 575, 578 (Okla.1966)).

As the Tenth Circuit observed in *Weyerhaeuser*:

As a general rule, anticipated profits "are too remote, speculative, and dependent upon uncertainties and changing circumstances to warrant a judgment for their loss." *City of Collinsville v. Brickey*, 115 Okla. 264, 242 P. 249, 253 (1925). To recover damages for lost profits, a plaintiff must therefore demonstrate "the fact of damage ... with reasonable certainty," and the "amount of damages may not be based upon mere speculation and conjecture." *Kobe, Inc. v. Dempsey Pump Co.*, 198 F.2d 416, 425-26 (10th Cir.1952); see also *City of Collinsville*, 242 P. at 253; 22 Am.Jur.2d Damages § 443.

*Id.* However, the difficulty in measuring such damages does not preclude recovery in all cases, as

“[a] claim for lost profits need not be proven with absolute certainty.” *Southwest Stainless, LP v. Sappington* 582 F. 3d 1176, 1184 (10<sup>th</sup> Cir. 2009). ““In essence, what a Plaintiff must show for the recovery of lost profits is sufficient certainty that reasonable minds might believe from a preponderance of the evidence that such damages were actually suffered.’ ” *Id.* (quoting *Boatsman v. Southwestern Bell Yellow Pages, Inc.*, 30 P.3d 1174, 1177 (Okla. Civ. App.2001)); *Florafax Int’l, Inc. v. GTE Market Resources, Inc.*, 933 P. 2d 282, 296 (Okla. 1997). Such damages are, by their nature, difficult to ascertain with a degree of certainty, and are generally based on estimates. *Malloy v. Monahan*, 73 F. 3d 1012, 1016 (10<sup>th</sup> Cir. 1996). However, such estimates must be based upon “judgment, not guesswork.” *Id.*

In this case, it is not disputed that Noll’s income as a real estate agent is based entirely on commissions from various real estate transactions. Plaintiffs and Defendant each present evidence regarding his average annual income before and after the two hip implant surgeries, and it is not disputed that he has returned to work in that capacity. Furthermore, as Defendant points out, Noll earned income as a real estate agent in 2009, and it submits evidence reflecting that his commissions earned as of August 10, 2009 were \$18,663.12, which exceeds the average earned during previous years. However, Plaintiffs’ expert witness, Darrell Harris<sup>6</sup>, has opined that Noll’s future earnings are expected to decline because his second hip surgery has resulted in decreased ability to perform the physical activities associated with his employment; moreover, Noll argues that others are less likely to work with him because he must utilize a cane. Defendant argues that utilizing these factors as the basis for the projected decline in his future income is too speculative to permit recovery of

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<sup>6</sup>Defendant repeats its arguments in support of its separate motion to exclude the testimony of Darrell Harris as inadmissible pursuant to Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U. S. 579 (1993). Defendant’s *Daubert* motion [Doc. No. 36] will be addressed in a separate order.

damages based on lost future income.

Having considered the parties' respective arguments and having examined the exhibits pertinent to this aspect of Defendant's motion, the Court concludes that Plaintiffs have submitted minimally sufficient evidence to create a disputed triable issue of fact on the question of Noll's alleged loss of future income. While the evidence may, as Defendant points out, be subject to challenge by Defendant's own expert witness and the other evidence in this case, it is sufficient to withstand summary judgment. Accordingly, the motion is DENIED as to this issue. Whether Plaintiffs have sufficient evidence to show a loss of future income caused by the alleged defect in the Device will be a question for trial.

## 2. Future medical expense:

Plaintiffs also seek recovery of Noll's anticipated future medical expenses. Although his second hip replacement surgery was successful and there has been no failure in the device implanted at that time, Plaintiffs contend that he suffered a condition known as "drop foot" or "foot drop" as a result of the second surgery. As explained by the parties, this condition is caused by damage to the sciatic nerve and results in pain, numbness, tingling, and an inability to raise or control the foot and toes. Plaintiffs contend this condition is permanent and that it is attributable to the second surgery which was required because of the failure of the Device. Defendant argues that Plaintiffs have submitted insufficient medical evidence to support this claim.

Subsequent to their initial briefing, each party submitted a supplemental brief on this issue. In their supplemental briefs, they debate the impact of a physical examination conducted by Dr. Gary Schick after the filing of respective dispositive motions. Plaintiffs contend that Dr. Schick's examination and subsequent deposition support their claim that Noll's condition is permanent, as

well as the previous medical opinion of one of Noll's physicians, Dr. S. V. Vaidya, who opined that Noll's condition is permanent. *See* affidavit of Dr. Vaidya, submitted as Plaintiffs' Response Exhibit 11.

Defendant argues that Plaintiffs have incorrectly characterized Dr. Schick's opinion, and contend that he did not opine that the drop foot condition could only have been caused by Noll's hip surgery. Defendant also points out that Dr. Schick testified Noll had made improvements since he examined him in 2008.

Although the parties disagree regarding Dr. Schick's testimony, they agree that he testified the nerve damage sustained by Noll normally takes as long as two years to heal and that a more accurate prognosis of permanency could be made at a later time. *See* Dr. Schick deposition, submitted as Defendant's Supplemental Exhibit 1, pp. 96-97. Because of the passage of time since Dr. Schick's last examination of Noll, whether his condition has improved remains to be seen and is not before the Court.

The Court concludes that the issue of whether damages for future medical expenses may be recovered cannot properly be determined via summary judgment. The parties have submitted conflicting evidence on this aspect of Plaintiffs' damages, and Plaintiffs' evidence is sufficient to withstand summary judgment. Accordingly, the motion is DENIED on this issue.

### 3. Punitive damages:

Defendant also seeks judgment on Plaintiffs' claim for recovery of punitive damages. Plaintiffs contend 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.

Plaintiffs rely on the Oklahoma statute which authorizes recovery of punitive damages where 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.<sup>7</sup> Defendant contends that the undisputed facts in the record establish that punitive damages are not recoverable in this case.

In their motion for summary judgment, Plaintiffs argued that the undisputed facts in the record establish that Defendant knew of the defect in the Device at the time it was placed on the market; they also argued that Defendant continued to market the Device after it received reports of alleged failures. In its Order ruling on that motion [Doc. No. 95], the Court found that the evidence failed to support Plaintiffs’ contentions and, in fact, supported the conclusion that Defendant exercised due diligence in analyzing and testing the Device before marketing the same. Order [Doc. No. 95] at pages 9 and 10. Furthermore, the Court concluded that the undisputed evidence in the record reflects that, after receiving initial reports of alleged failures of the Device, Defendant took steps to notify customers and surgeons of potential problems; furthermore, Defendant quickly took steps to modify the Device to avoid additional problems. Order at pages 10-11. The Court need not repeat its discussion of the punitive damages issue herein, but adopts and incorporates pages 9 through 11 of the previous Order [Doc. No. 95].

In the Order ruling on Plaintiffs’ summary judgment motion, the Court stated that it would address Defendant’s contention that punitive damages are not recoverable as a matter of law in connection with its ruling on Defendant’s summary judgment motion. The Court has again reviewed the evidence presented by the parties. Construing that evidence in the light most favorable to

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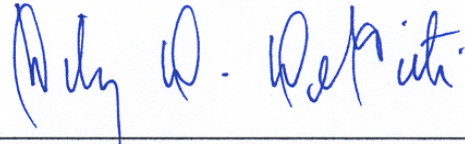
<sup>7</sup>Although the statute also permits punitive damages in situations in which a defendant acted intentionally or maliciously, Plaintiffs do not rely on such circumstances in this case; they argue only that Defendant acted with reckless disregard for the rights of others.

Plaintiffs, the Court concludes that the record does not support recovery of punitive damages in this case. Accordingly, Defendant's motion is GRANTED as to this issue.

V. Conclusion:

For the reasons set forth herein, Defendant's summary judgment motion [Doc. No. 34] is granted in part and denied in part. The motion is granted as to Plaintiffs' claim for recovery of punitive damages; in all other respects, the motion is denied.

IT IS SO ORDERED this 15<sup>th</sup> day of July, 2010.



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TIMOTHY D. DEGIUSTI  
UNITED STATES DISTRICT JUDGE