

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

TAMMIE L. WILLIAMS, et al.,

Plaintiffs,

v.

Case No.: 2:08-cv-910

JUDGE SMITH

Magistrate Judge Deavers

BAUSCH & LOMB COMPANY, et al.,

Defendants.

OPINION AND ORDER

Plaintiffs Tammie and Charles Williams initiated this action against Defendants Bausch & Lomb Incorporated (“Bausch & Lomb”), pSivida U.S. Inc. (“pSivida”), David G. Callanan, M.D., Texas Retina Associates, and two John Does, alleging claims for strict liability, negligence, breach of implied warranty, breach of express warranty, negligent misrepresentation, intentional infliction of emotional distress, and loss of consortium.¹ These claims arise from the surgical insertion of a medical device into Ms. Williams’ right eye and the subsequent removal of the device after it allegedly broke in her eye. This matter is currently before the Court on the motions of Defendants Bausch & Lomb and pSivida for partial summary judgment on Plaintiffs’ request for an award of noneconomic damages. These two motions have been fully briefed by the parties and are ripe for disposition. For the reasons that follow, the Court **GRANTS** the motions for partial summary judgment of Defendants Bausch & Lomb and pSivida.

¹ The claims against Dr. Callanan and Texas Retina Associates were dismissed without prejudice by this Court on August 28, 2009 (doc. 38).

I. BACKGROUND

In 1996, Ms. Williams began to experience vision problems and was diagnosed with cataracts in both of her eyes. The cataracts were removed, and her vision improved. But in 1998, she was diagnosed with an eye disease known as uveitis, which involves the inflammation of the eye. Ms. Williams' initial treatment for this condition involved the frequent injection of a steroid directly into her eyes.

In May 2001, Ms. Williams agreed to participate in a clinical research study sponsored by Defendant Bausch & Lomb, which, along with Defendant pSivida, designed and manufactured the optometric device at issue in this case, the Retisert Intravitreal Fluocinolone Acetone Implant (the "Implant"). As part of this study, Ms. Williams agreed to have the Implant surgically inserted into her right eye for treatment of uveitis affecting the posterior segment of the eye. The Implant is designed to release an anti-inflammatory drug in the eye and thereby eliminate the need for the frequent, and painful, steroid injections. On May 21, 2001, Ms. Williams signed a consent form permitting the Implant to be placed in her eye, and the surgery was performed that day. An Implant was not placed in her left eye.

In October 2006, the Implant in Ms. Williams' right eye separated from its original position. Ms. Williams underwent surgery to remove the Implant. After the removal of the Implant, Ms. Williams experienced a complete loss of vision in her right eye.

In September 2008, Plaintiffs filed suit against Defendants, asserting the following seven claims in their Complaint: (1) strict liability; (2) negligence; (3) breach of implied warranty; (4) breach of express warranty; (5) negligent misrepresentation; (6) intentional infliction of

emotional distress; and (7) loss of consortium. Plaintiffs' Complaint includes a prayer for relief that seeks general damages in an amount in excess of \$100,000.

Defendants Bausch & Lomb and pSivida previously moved to dismiss Counts Two, Three, Four, Five, and Six of Plaintiffs' Complaint, arguing that these non-statutory claims fail to state a claim upon which relief may be granted. Specifically, Defendants argued that Ohio's comprehensive product liability statutes, Ohio Revised Code §§ 2307.71 through 2307.80, constitute Plaintiffs' exclusive remedy, as stated in Ohio Revised Code § 2307.71, and any claims which fall outside that statutory structure must be dismissed. Defendants further argued that all of Plaintiffs' claims are product liability claims as defined in Ohio Revised Code § 2307.71(A)(13) and therefore subject to the exclusive remedies provided in Ohio's product liability statutes. This Court agreed, and accordingly dismissed without prejudice Plaintiffs' claims for negligence, breach of implied warranty, breach of express warranty, negligent misrepresentation, and intentional infliction of emotional distress (counts two through six) (Doc. 39). The Court granted Plaintiffs leave to re-plead these claims pursuant to the Ohio Products Liability Act. *Id.*

Subsequently, Defendants Bausch & Lomb and pSivida filed their motions for partial summary judgment that are currently pending before the Court. Pursuant to Ohio Revised Code § 2315.18(E)(2),² both Defendants seek partial summary judgment on the issue of whether the statutory cap on noneconomic damages set forth in § 2315.18(B)(2) applies in this case.

² Ohio Revised Code § 2315.18(E)(2) provides that, before a jury trial in certain tort actions to recover damages for injury or loss to person or property, a party may seek summary judgment as to the nature of the alleged injury or loss to person or property, for the purpose of determining the applicability of the statutory cap on noneconomic damages set forth in Ohio Rev. Code § 2315.18(B)(2).

II. SUMMARY JUDGMENT STANDARD

The standard governing summary judgment is set forth in Federal Rule of Civil Procedure 56(c)(2), which provides as follows: “The judgment sought should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.”

Summary judgment will not lie if the dispute about a material fact is genuine; “that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.”

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Summary judgment is appropriate, however, if the opposing party fails to make a showing sufficient to establish the existence of an element essential to that party’s case and on which that party will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *see also Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986).

When reviewing a summary judgment motion, the Court must draw all reasonable inferences in favor of the nonmoving party, and must refrain from making credibility determinations or weighing the evidence. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150-51 (2000).³ The Court disregards all evidence favorable to the moving party that the

³ *Reeves* involved a motion for judgment as a matter of law made during the course of a trial under Fed. R. Civ. P. 50 rather than a pretrial summary judgment under Fed. R. Civ. P. 56. Nonetheless, standards applied to both kinds of motions are substantially the same. One notable difference, however, is that in ruling on a motion for judgment as a matter of law, the Court, having already heard the evidence admitted in the trial, views the entire record, *Reeves*, 530 U.S. at 150. In contrast, in ruling on a summary judgment motion, the Court will not have heard all of the evidence, and accordingly the non-moving party has the duty to point out those portions of the paper record upon which it relies in asserting a genuine issue of material fact, and the court need not comb the paper record for the benefit of the nonmoving party. *In re Morris*, 260 F.3d 654, 665 (6th Cir. 2001). As such, *Reeves* did not announce a new standard of review for summary judgment motions.

jury would not be required to believe. *Id.* Stated otherwise, the Court must credit evidence favoring the nonmoving party as well as evidence favorable to the moving party that is uncontroverted or unimpeached, if it comes from disinterested witnesses. *Id.*

The Sixth Circuit Court of Appeals has recognized that *Liberty Lobby*, *Celotex*, and *Matsushita* have effected “a decided change in summary judgment practice,” ushering in a “new era” in summary judgments. *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1476 (6th Cir. 1989). The court in *Street* identified a number of important principles applicable in new era summary judgment practice. For example, complex cases and cases involving state of mind issues are not necessarily inappropriate for summary judgment. *Id.* at 1479.

Additionally, in responding to a summary judgment motion, the nonmoving party “cannot rely on the hope that the trier of fact will disbelieve the movant’s denial of a disputed fact, but must ‘present affirmative evidence in order to defeat a properly supported motion for summary judgment.’” *Id.* (quoting *Liberty Lobby*, 477 U.S. at 257). The nonmoving party must adduce more than a scintilla of evidence to overcome the summary judgment motion. *Id.* It is not sufficient for the nonmoving party to merely “‘show that there is some metaphysical doubt as to the material facts.’” *Id.* (quoting *Matsushita*, 475 U.S. at 586).

Moreover, “[t]he trial court no longer has a duty to search the entire record to establish that it is bereft of a genuine issue of material fact.” *Id.* at 1479-80. That is, the nonmoving party has an affirmative duty to direct the court’s attention to those specific portions of the record upon which it seeks to rely to create a genuine issue of material fact. *In re Morris*, 260 F.3d 654, 665 (6th Cir. 2001).

III. DISCUSSION

The issue presented by the pending motions is whether the statutory cap on noneconomic damages set forth in Ohio Revised Code § 2315.18(B)(2) applies to Plaintiffs' claims against Defendants. Defendants argue that any award of noneconomic damages in this case would be capped pursuant to this provision, and the exceptions to this limitation set forth in Ohio Revised Code § 2315.18(B)(3) do not apply. Conversely, Plaintiffs argue that their request for noneconomic damages is not subject to the limitations set forth in § 2315.18(B)(2) because the facts of this case fit squarely within the exception to this limitation.

Section 2315.18(B)(2) provides that, except as provided in § 2315.18(B)(3), the recovery of noneconomic damages in a tort action under this section is limited to the greater of (1) \$250,000, or (2) three times the economic damages up to a maximum of \$350,000, for a single plaintiff, or \$500,000 per occurrence. However, for "catastrophic injuries," there is no damages limit. *Arbino v. Johnson & Johnson*, 880 N.E.2d 420, 433 (2007) (citing Ohio Rev. Code § 2315.18(B)(3)).⁴

Section 2315.18(B)(3) states as follows:

There shall not be any limitation on the amount of compensatory damages that represents damages for noneconomic loss that is recoverable in a tort action to recover damages for injury or loss to person or property if the noneconomic losses of the plaintiff are for either of the following:

(a) Permanent and substantial physical deformity, loss of use of a limb, or loss of a bodily organ system;

⁴ The parties seem to suggest that the Ohio General Assembly used the term "catastrophic injuries" to define what injuries are exempted from the statutory damages cap. But this term does not appear in the statute and was simply used as a general reference by the Ohio Supreme Court in *Arbino* to characterize the type of injury that would preclude the application of the cap.

(b) Permanent physical functional injury that permanently prevents the injured person from being able to independently care for self and perform life-sustaining activities.

The parties do not dispute that, absent the application of an exception set forth in § 2315.18(B)(3), any award of noneconomic damages in connection with Plaintiffs' product liability claims would be capped by § 2315.18(B)(2). Thus, the dispute ultimately centers on whether the exception to this limitation applies. Section 2315.18(B)(3) provides that the cap on noneconomic damages does not apply if *either* subsection (a) or (b) applies. Plaintiffs argue that both subsection (a) and (b) apply here. Thus, the court will address each possible exception in turn.

A. Applicability of Section 2315.18(B)(3)(a)

As outlined above, Section 2315.18(B)(3)(a) provides that the noneconomic damages cap does not apply if the damages are for permanent and substantial physical deformity, loss of use of a limb, or loss of a bodily organ system. According to Plaintiffs, Ms. Williams has suffered the loss of a bodily organ system. Plaintiffs argue that her total and permanent loss of vision in her right eye, combined with her poor vision in her left eye, constitutes the loss of a bodily organ system. Alternatively, Plaintiffs contend that Ms. Williams has suffered the loss of a bodily organ system even if only her right eye is considered. Defendants argue that Ms. Williams has not lost a bodily organ system.

The Ohio Revised Code does not define the term "bodily organ system" for the purpose of this section, and there is a dearth of case law defining or applying it. Stedman's Medical Dictionary (27th ed. 2000) ("Stedman's") defines an "organ" as "[a]ny part of the body exercising a specific function, as of respiration, secretion, or digestion[.]" and defines an "eye" as

the “organ of vision that consists of the eyeball and the optic nerve.” Under these definitions, each eye constitutes an “organ.” But the statute at issue addresses the loss of an “organ system.” If the Ohio General Assembly sought to preclude the application of the damages cap for the loss of any organ, such as one eye, then it would not have included the word “system” after the word “organ” in the statute. Stedman’s defines a “system” as a “consistent and complex whole made up of correlated and semiindependent parts. A complex of functionally related anatomic structures.” Similarly, the Oxford English Dictionary (2d ed. 1989), defines a “system” in pertinent part as a “set of organs or parts in an animal body of the same or similar structure, or subserving the same function[.]”

Applying these definitions, which are consistent with the plain meaning of the term, the body’s ocular system constitutes a bodily organ system. One does not need to be a medical doctor to understand that even though each eye can function independently, a person’s two eyes work in concert, or as a system, to provide the person with a visual account of the surrounding world. Hence, the loss of vision in one eye does not result in the loss of a bodily organ system, if the other eye is functional. In other words, even though a person’s vision is diminished if he or she loses the ability to see in one eye, the ocular system would otherwise remain operational. The Court additionally finds that the “loss of a bodily organ system” language only applies to permanent and total losses, as the Ohio Supreme Court has made clear that the exceptions to the damages cap only account for circumstances characterized by pain and suffering that is “traumatic, extensive, and chronic,” and that which involve the most severely injured. *See Arbino*, 880 N.E.2d at 435.

There is no dispute that evidence in the record indicates that Ms. Williams has lost the ability to see, at a functional level, out of her right eye. As to Ms. Williams' left eye, Defendants argue that the status of this eye is irrelevant to the resolution of the pending motions. The Court disagrees. The status of her left eye is pertinent because it forms part of her vision system. Although the statute at issue does not expressly account for the fact that many people have diminished vision in one or both of their eyes, it is clear to the Court that if a person with only one functioning eye loses the ability to see out of that eye, then that person has lost the use of his or her vision system. Thus, the issue here is whether the injury to Ms. Williams' right eye resulted in the loss of her vision system, taking into account Ms. Williams' ability to see out of her left eye.

Plaintiffs assert that record evidence indicates that she is or has been "legally blind." In support, Plaintiffs cite Ohio Revised Code § 3304.28(B) as providing the applicable definition of "legal blindness" for determining lost eyesight under § 2315.18(B)(3). Section 3304.28(B) applies to §§ 3304.28 to 3304.34, which concern the operation of vending facilities by visually impaired persons, and states as follows:

"Blind" means either of the following:

- (1) Vision twenty/two hundred or less in the better eye with proper correction;
- (2) Field defect in the better eye with proper correction which contracts the peripheral field so that the diameter of the visual field subtends an angle no greater than twenty degrees.

Although § 3304.28(B) technically does not apply to § 2315.18(B)(3), the definition contained therein is accepted as the legal definition of "blind" in Ohio. *See* Ohio Rev. Code § 955.011(B)(2) (same definition applying to provisions pertaining to use of assistance dogs); Ohio

Rev. Code § 5109.15 (same definition applying to provisions pertaining to blind-made products); *see also State ex rel. AutoZone, Inc. v. Indus. Comm.*, 883 N.E.2d 372, 375 (2008) (citing the definition of blind contained in § 3304.28(B)(1) for the purpose of analyzing whether a worker had lost the sight of an eye in the workers' compensation context).

According to Plaintiffs, Ms. Williams has been found "legally blind" in both eyes under this definition, and therefore she has demonstrated that she has lost her vision system. In support of this contention, Plaintiffs cite two letters that were signed by physicians who examined Ms. Williams, and the testimony of Dr. Careen Lowder, who is an ophthalmologist at the Cleveland Clinic and Ms. Williams' treating physician. One letter, signed by Dino D. Klisovic, M.D., and dated November 20, 2006, states that Ms. Williams is "legally blind," and that her "[b]est corrected visual acuity is HM in the right eye and 20/200 in the left eye. This permanent level of blindness is due to Uveitis Iridocyclitis Nos and its complications." (Doc. 69-1). The record also contains a letter, dated October 23, 2009, signed by Lisa M. Borkowski, M.D., stating that Ms. Williams was legally blind in both eyes for most or all of 2009. Furthermore, at her deposition, Dr. Lowder testified that, in November and December 2009, Ms. Williams had a visual acuity of 20/400 in her left eye.

Certainly, if someone with some functional degree of vision becomes permanently blind in both eyes, that person has lost the use of his or her vision system, for the purpose of the damages cap provision at issue here. But no reasonable jury could find, based on the evidence in the record, that Ms. Williams is permanently blind in both eyes and therefore has lost the use of her vision system. Since writing the October 23, 2009 letter, Dr. Borkowski has essentially recanted her opinion that Ms. Williams is blind in both eyes. In a November 9, 2009 letter to Dr.

Careen Lowder, Dr. Borkowski stated that while she initially filled out the form addressing Ms. Williams' blindness, Ms. Williams' vision should be checked with a certain type of corrective lens before any blindness determination. Implicit in this letter is a recognition that Ms. Williams had not been checked with this type of corrective lens when the blindness determination was made in October 2009.

Furthermore, although Dr. Lowder testified that Ms. Williams demonstrated a left eye visual acuity of 20/400 in November and December 2009, she also testified that she viewed this level of visual acuity as temporary, and that she expected Ms. Williams' vision to improve with medical treatment that would reduce the inflammation in her eye. Moreover, Ms. Williams testified at her May 2009 deposition that her visual acuity in her left eye was 20/70 with correction, and she testified in her October 2009 affidavit that, while her level of vision fluctuates, her visual acuity in her left eye is 20/70 with correction when she does not have inflammation. The accuracy of this testimony has been confirmed by the briefing regarding the pending motions.

In sum, Dr. Borkowski recanted her legal blindness finding, and Dr. Klisovic's 2006 "permanent" legal blindness finding has been undisputedly discredited, in view of Plaintiffs' concession that Ms. Williams has since demonstrated a visual acuity of 20/70 in her left eye. And even though Dr. Lowder testified that Ms. Williams exhibited a visual acuity of 20/400 in her left eye at two recent visits to her office, she also testified that she did not view this circumstance as permanent. Therefore, Plaintiffs have not created a genuine issue of material fact as to whether she has lost her ocular system.

Accordingly, the Court finds that Ohio Revised Code § 2315.18(B)(3)(a) does not apply here as a matter of law.

B. Applicability of Section 2315.18(B)(3)(b)

As outlined above, Section 2315.18(B)(3)(b) provides that the noneconomic damages cap does not apply if the damages are for permanent physical functional injury that permanently prevents the injured person from being able to independently care for self and perform life-sustaining activities. Plaintiffs argue that they have presented evidence demonstrating that Ms. Williams has suffered an injury that permanently prevents her from being able to independently care for herself and perform life-sustaining activities without assistance. Essentially, Plaintiffs contend that her vision is so diminished that she cannot independently care for herself or perform life-sustaining activities without assistance. Defendants argue that Ms. Williams is not unable to independently care for herself or perform life-sustaining activities.

In support of their pending motions, Defendants cite the deposition testimony of Dr. Lowder, who testified in detail regarding the condition of Ms. Williams' eyes. Dr. Lowder began to treat Ms. Williams in November 2006, and she continues to treat Ms. Williams. At Ms. Williams' visit in November 2006, the corrected visual acuity in her left eye was evaluated at 20/70, and her right eye's visual acuity was limited to "hand motion." Ms. Williams' field of vision was full; it was "excellent." (Lowder Dep., p. 14). Dr. Lowder's testimony indicates that Ms. Williams' vision in her right eye has remained limited to "hand motion," and Dr. Lowder considers her blind in the right eye. *Id.* at 34. Dr. Lowder's testimony further indicates that, during her treatment of Ms. Williams, Ms. Williams' vision in her left eye generally remained around 20/70, save a recent instance of an "acute flare up." *See id.* at 70. Dr. Lowder testified

that it is not unusual for patients with uveitis to have acute flare ups, and that typically these flare ups are fairly easily treatable under proper medical care. *Id.* at 73. Dr. Lowder opined that Ms. Williams has no restrictions on her activities of daily living, and that her vision problems should not prevent her from independently performing her activities of daily living. Dr. Lowder specifically opined that Ms. Williams does not have a permanent physical functional injury that permanently prevents her from being able to independently care for herself and perform life-sustaining activities.

At her deposition, taken in May 2009, Ms. Williams testified that her visual acuity in her left eye was 20/70, and that she held a valid Ohio driver's license, which she renewed in February 2008. When she renewed her driver's license, Ms. Williams was required to complete a vision test. Her driver's licence has corrective lenses and daytime driving restrictions.⁵ Ms. Williams testified that, even though she holds a valid driver's license, she has not driven a vehicle since the Implant broke in her eye. Additionally, Ms. Williams testified at her deposition that she is able to dress herself, brush her teeth, wash her hands, comb her hair, and walk without assistance.

Despite this testimony, Plaintiffs point to their own affidavits, dated October 29, 2009, as allegedly creating a genuine issue of fact as to the applicability of § 2315.18(B)(3)(b). Plaintiffs' affidavits state that Ms. Williams cannot independently care for herself, as she must rely upon others to assist her in activities of daily living. But Ms. Williams' affidavit also indicates that,

⁵ Under Ohio Administrative Code § 4501:1-1-20(C)(2), persons with monocular vision whose visual acuity is poorer than 20/30, but not worse than 20/60, are issued a license restricted to daytime driving, and such persons unable to attain acuity of at least 20/60 must be denied a license.

when inflammation is minimized, her visual acuity in her left eye is 20/70 with corrective lenses. This testimony is entirely consistent with the testimony of Dr. Lowder, which explained the correlation between Ms. Williams' ability to see out of her left eye and the temporary inflammation affecting that eye.

Although evidence indicates that Ms. Williams experienced a "flare up" in inflammation in her left eye toward the end of 2009, which may explain the discrepancies between Ms. Williams' deposition and her more recent affidavit, the only competent evidence relating to the permanency of the condition is the testimony of Dr. Lowder. Dr. Lowder testified that Ms. Williams is not permanently prevented from independently caring for herself or performing life-sustaining activities. Plaintiffs speculate that Ms. Williams may completely lose her vision in the future. But speculation is not a basis for creating a genuine issue of fact. *See Bryant v. Commonwealth of Kentucky*, 490 F.2d 1273, 1274 (6th Cir. 1974) ("mere conclusory and unsupported allegations, rooted in speculation" do not meet burden to withstand summary judgment).

In the final analysis, Plaintiffs have failed to produce sufficient evidence demonstrating that, as a result of her vision problems, Ms. Williams is permanently disabled as described in the applicable statute. Evidence in the record indicates that Plaintiffs' lives have been negatively impacted by Ms. Williams' vision problems, regardless of whether it was caused in part by Defendants' product or entirely by the uveitis condition. But insufficient evidence has been presented to demonstrate a genuine issue of fact as to whether she has suffered the type of catastrophic injury that would preclude the application of the damages cap. Therefore, the Court resolves that Ohio Revised Code § 2315.18(B)(3)(b) does not apply here as a matter of law.

Because neither Ohio Revised Code § 2315.18(B)(3)(a) nor (b) apply here, any award of noneconomic damages in this case would be subject to the cap set forth in Ohio Revised Code § 2315.18(B)(2).⁶

IV. DISPOSITION

For the foregoing reasons, the Court **GRANTS** the motions of Defendants Bausch & Lomb Incorporated and pSivida U.S. Inc. for partial summary judgment on Plaintiffs' request for noneconomic damages (Docs. 41 and 43).

The Clerk shall remove Documents 41 and 43 from the Court's pending motions list.

IT IS SO ORDERED.

s/ George C. Smith
GEORGE C. SMITH, JUDGE
UNITED STATES DISTRICT COURT

⁶ The Court notes that although it has found that the statutory cap applies here to limit any noneconomic damages awarded, this finding has no bearing on the merits of Plaintiffs' claims against Defendants.