Ernesteen Jones, Plaintiff,

v.

Novartis Pharmaceuticals Corporation, Defendant.

United States District Court, N.D. Alabama, Southern Division.
February 10, 2017
Slip Copy
2017 WL 553134

Attorneys and Law Firms

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MEMORANDUM OPINION

VIRGINIA EMERSON HOPKINS, United States District Judge

I. INTRODUCTION

***1** Pending before the Court is Defendant Novartis Pharmaceuticals Corporation ("Novartis")'s Motion for Summary Judgment (Doc. 106). On January 26, 2017, this Court issued an Order (doc. 195) granting in full and in part Novartis' Motions To Strike the testimony of five of Plaintiff Ernesteen Jones ("Jones")'s expert witnesses. The Court held that none of these experts offered a general or specific causation opinion that was sufficiently reliable under Federal Rule of Evidence 702 to render their causation opinions admissible.

The Motion for Summary Judgment (Doc. 106) has been fully briefed and is now ripe for disposition. Because evidence of causation is an essential element of each of Jones's remaining claims, Novartis' Motion for Summary Judgment is due to be **GRANTED**.

II. SUMMARY JUDGMENT STANDARD

Under Federal Rule of Civil Procedure 56, summary judgment is proper if there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552, 91 L.Ed. 2d 2265 (1986) ("[S]ummary judgment is proper if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.") (internal quotation marks omitted).

The party requesting summary judgment always bears the initial responsibility of informing the Court of the basis for its motion and identifying those portions of the pleadings or filings that it believes demonstrate the absence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323, 106 S. Ct. at 2553. Once the moving party has met its burden, Rule 56(c) requires the non-moving party to go beyond the pleadings in answering the movant. [1] *Id.* at 324, 106 S. Ct. at 2553. By its own affidavits—or by the depositions, answers to interrogatories, and admissions on file—it must designate specific facts showing that there is a genuine issue for trial. *Id.*

1 When *Celotex* was decided, FED. R. CIV. P. 56(e) encompassed this express requirement, but now this concept is covered by the language provided for under FED. R. CIV. P. 56(c).

The underlying substantive law identifies which facts are material and which are irrelevant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 2510, 91 L.Ed. 2d. 202 (1986). All reasonable doubts about the facts and all justifiable inferences are resolved in favor of the non-movant. *Chapman v. AI Transport*, 229 F.3d 1012, 1023 (11th Cir. 2000). Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. *Anderson*, 477 U.S. at 248, 106 S. Ct. at 2510. A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* If the evidence presented by the non-movant to rebut the moving party's evidence is merely colorable, or is not significantly probative, summary judgment may still be granted. *Id.* at 249, 106 S. Ct. at 2511.

***2** How the movant may satisfy its initial evidentiary burden depends on whether that party bears the burden of proof on the given legal issues at trial. *Fitzpatrick v. City of Atlanta*, 2 F.3d 1112, 1115 (11th Cir. 1993). If the movant bears the burden of proof on the given issue or issues at trial, then it can only meet its burden on summary judgment by presenting *affirmative* evidence

showing the absence of a genuine issue of material fact—that is, facts that would entitle it to a directed verdict if not controverted at trial. *Id.* (citing *United States v. Four Parcels of Real Property*, 941 F.2d 1428, 1438 (11th Cir. 1991)). Once the moving party makes such an affirmative showing, the burden shifts to the non-moving party to produce "significant, probative *evidence* demonstrating the existence of a triable issue of fact." *Id.* (emphasis added).

For issues on which the movant does not bear the burden of proof at trial, it can satisfy its initial burden on summary judgment in either of two ways. *Id.* at 1115-16. First, the movant may simply show that there is an absence of evidence to support the non-movant's case on the particular issue at hand. *Id.* at 1116. In such an instance, the non-movant must rebut by either (1) showing that the record in fact contains supporting evidence sufficient to withstand a directed verdict motion, or (2) proffering evidence sufficient to withstand a directed verdict motion at trial based on the alleged evidentiary deficiency. *Id.* at 1116-17. When responding, the non-movant may no longer rest on mere allegations; instead, it must set forth evidence of specific facts. *Lewis v. Casey*, 518 U.S. 343, 358, 116 S. Ct. 2174, 2183, 135 L.Ed. 2d 606 (1996). The second method a movant in this position may use to discharge its burden is to provide affirmative *evidence* demonstrating that the non-moving party will be unable to prove its case at trial. *Fitzpatrick*, 2 F.3d at 1116. When this occurs, the non-movant must rebut by offering *evidence* sufficient to withstand a directed verdict at trial on the material fact sought to be negated. *Id.*

III. UNDISPUTED MATERIAL FACTS [2]

[2] Keeping in mind that, when deciding a motion for summary judgment, the Court must view the evidence and all factual inferences in the light most favorable to the party opposing the motion, the Court provides the following statement of facts. *See Optimum Techs., Inc. v. Henkel Consumer Adhesives, Inc.*, 496 F.3d 1231, 1241 (11th Cir. 2007) (observing that, in connection with summary judgment, a court must review all facts and inferences in a light most favorable to the non-moving party). This statement does not represent actual findings of fact. *See In re Celotex Corp.*, 487 F.3d 1320, 1328 (11th Cir. 2007). Instead, the Court has provided this statement simply to place the Court's legal analysis in the context of the particular case or controversy.

Novartis markets Reclast in the United States. In August 2007, the Food and Drug Administration ("FDA") approved Reclast for the treatment of postmenopausal osteoporosis. Reclast is a five-milligram dose of zoledronic acid indicated for osteoporosis and for treatment of Paget's disease of bone. Reclast is one drug in a class of bisphosphonate ("BP") drugs and is administered intravenously once a year. Osteoporosis, the disease for which BPs are prescribed, commonly causes hip and femur fractures.

Drug sponsors seeking approval from the FDA must provide a body of evidence from clinical trials that adequately characterizes the product's safety profile. Rare adverse events are often not detected during large clinical trials because there is not a sufficient patient experience. A drug manufacturer has an obligation to engage in pharmacovigilance or safety surveillance to identify and evaluate safety signals associated with a drug and stay abreast of scientific literature. Novartis, through its routine pharmacovigilance review, surveyed literature referencing Reclast. The primary clinical study submitted by Novartis to support the efficacy of Reclast was Study 2301, also known as the HORIZON pivotal fracture trial.

***3** In June 2008, the FDA informed Novartis that it was aware of reports of the occurrence of subtrochanteric hip fractures in patients using BPs and asked Novartis to submit all hip and femoral fracture case reports. The FDA made the same request to the manufacturers of the oral BPs indicated for osteoporosis. At the time of the FDA's information request in June 2008, there were no published reports in the medical literature linking Reclast to subtrochanteric or disphyseal fractures. Novartis submitted its findings to the FDA in July 2008. The FDA also announced it was working closely with outside experts, including a special task force convened by the American Society of Bone and Mineral Research ("ASBMR"). Prior to 2010, the FDA had not required an AFF warning on any bisphosphonate drug.

On March 17, 2010, the FDA requested, as a follow-up of its June 2008 request, that Novartis "provide all findings from any analyses which [Novartis] had and study reports and the status of any ongoing or planned mechanistic, epidemiologic, or clinical studies regarding subtrochanteric femur fractures." (Doc. 166-42 at ¶ 78). On March 24, 2010, the FDA requested that Novartis submit a summary of all available controlled efficacy

and safety data regarding long term use of Reclast for the treatment and/or prevention of osteoporosis and an opinion and discussion of whether either restricting the duration of use or implementing a drug holiday might be beneficial for patients requiring long-term treatment. In response, Novartis informed the FDA that the recommendation of a drug holiday is not supported by the available data in the prospective and well-controlled 3-year extension trial.

In September 2010, the ASBMR Task Force developed a case definition for AFFs and found that "the incidence of [AFFs] associated with BP therapy for osteoporosis appears to be very low, particularly compared with the number of vertebral, hip, and other fractures that are prevented by BPs. Moreover, a causal association between BPs and atypical fractures has not been established." The report acknowledged that the risk-benefit ratio favors BP treatment in women at high risk of fracture and recommended that physicians and patients should be made aware of the possibility of AFF through a change in labeling of BPs. On October 13, 2010, following the ASBMR report, the FDA announced that it had decided to require information on the risk of AFF to be added to the Warnings and Precautions Section of the labels of all BP drugs approved for the prevention or treatment of osteoporosis. The January 2011 package insert for Reclast stated that the "safety and effectiveness of Reclast for the treatment of osteoporosis is based on clinical data of three years duration."

Dr. Traylor, Jones's treating physician, prescribed Reclast to treat her osteoporosis. She received three annual infusions of Reclast; specifically, on February 10, 2009, March 16, 2010, and March 17, 2011. Dr. Traylor testified that he prescribes BPs for his patients to prevent fractures and finds Reclast to be an effective drug. He believes that AFFs are uncommon and the incidence of AFFs is much lower than osteoporotic fractures. He also believes that BPs, like Reclast, prevent many more osteoporotic fractures than the number of AFFs allegedly associated with such medications. Dr. Traylor has prescribed Reclast thousands of times and still prescribes Reclast today, even with the knowledge of reported association with AFFs. As of the date of his deposition in March 2015, Dr. Traylor believed that Reclast was a standard of care treatment for osteoporosis.

When Dr. Traylor first prescribed Reclast for Jones in 2009, she was at a high risk of fracture and had a number of risk fracture factors, including age, sex, race, postmenopausal status, and history of steroid use. At the time of her third infusion, Jones still had persistent osteoporotic T-scores and persistent osteoporosis. She also had a history of poor compliance with taking oral BPs, which she had been prescribed. Dr. Traylor prescribes Reclast for patients who are having compliance issues with oral BPs and believes that an important benefit of Reclast is that it is administered intravenously. Dr. Traylor prescribed Reclast to Jones because he believed at the time of her three infusions that the benefits of the drug outweighed the risks. At the time of Jones's third Reclast infusion in March 2011, the Reclast prescribing information contained a warning regarding AFF in the Warnings and Precautions section and a statement regarding duration of use in the Important Limitations of Use Section.

***4** On October 26, 2011, Jones heard a loud crack and fell on her way to the bathroom. She was treated in the emergency room at St. Vincent's Hospital by Dr. James Worthen, a board-certified orthopaedic surgeon. Dr. Worthen testified that he believed the x-rays revealed a complete, transverse disphyseal femur fracture. Jones alleges her left and right femoral fractures were caused by her Reclast injections.

In 2016, the ASBMR published a task force report providing a suggested approach for long-term BP use, not replacing the need for clinical judgment, that suggested (1) providing Reclast for three years via three annual infusions; (2) after three years, assessing whether the patient remains at high risk for fracture; (3) if the patient is not at high risk, "consider" stopping therapy and reassess every 2-3 years; and (4) if the patient remains at high risk, consider continuing Reclast for another three years for a total of six years. The Reclast treatment that Jones received was in accordance with the 2016 ASBMR report.

IV. ANALYSIS

In her Amended Complaint (doc. 54), Plaintiff asserts four claims against Novartis: claims under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") (Count I), Failure to Warn (Count II), Negligence and Wantonness (Count III), and Breach of Warranty of Merchantability (Count IV). In her Response to Novartis' Motion for Summary Judgment, Jones "voluntarily

withdr [ew] her defective design and warranty claims" and "expressly reserve[d] her AEMLD and negligence/ wantonness claims." (Doc. 166-42) at 47 n. 46. Plaintiff also clarified that her AEMLD and negligence/ wantonness claims are all based on an alleged failure to warn. *Id.* at 46.

A. Alabama Extended Manufacturer's Liability Doctrine

The Alabama Supreme Court has expressly modeled the AEMLD on § 402A of the Second Restatement of Torts and the landmark line of common-law cases beginning with Judge Cardozo's *Macpherson v. Buick Motor Co.*, 217 N.Y. 382, 111 N.E. 1050 (1916), that allow consumer tort recovery without direct proof of negligence in the manufacturing process. *See Atkins v. American Motors Corp.*, 335 So. 2d 134, 137-38 (Ala. 1976); *see also* Restatement of the Law, Third, Torts: Products Liability, § 3, at 111.

To establish liability under the AEMLD, a plaintiff must show:

> (1) he suffered injury or damages to himself or his property by one who [sold] a product in a defective condition unreasonably dangerous to the plaintiff, as the ultimate user or consumer, if
>
> (a) the seller [was] engaged in the business of selling such a product, and
>
> (b) it [was] expected to and [did] reach the user or consumer without substantial change in the condition in which it was sold.

Bodie v. Purdue Pharma. Co., 236 Fed.Appx. 511, 518 (11th Cir. 2007) [3] (citing *Morguson v. 3M Co.*, 857 So. 2d 796, 800 (Ala. 2003)). A plaintiff must present evidence that the defendant "put[ ] on the market a product which is not reasonably safe, and the plaintiff is injured *as a result* of a contemplated use of that product." *Atkins*, 335 So. 2d at 140 (emphasis added); *see also Taylor v. General Motors Corp.*, 707 So. 2d 198, 201 (Ala. 1997).

3 In the Eleventh Circuit, unpublished decisions are not binding precedent, but they may be cited as persuasive authority. 11th Cir. R. 36-2.

For AEMLD cases involving prescription drugs, "which are inherently unsafe, the adequacy of [a drug's] accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous." *Bodie*, 236 Fed.Appx. at 518 (internal quotations omitted) (citing *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304 (Ala. 1984)). The burden is on the plaintiff in an AEMLD action to show "that which rendered the product in such an unfit condition in fact caused the injury. The plaintiff's burden will not be sustained without evidence to support the conclusion that the product is defective." *Sears, Roebuck & Co., Inc. v. Haven Hills Farm, Inc.*, 395 So. 2d 991, 995 (Ala. 1981), *declined to follow on other grounds by Ex Parte General Motors Corp.*, 769 So. 2d 903 (Ala. 1999). A plaintiff must prove both that the product was defective and that the plaintiff's injury was causally related to the product's defective condition. *Verchot v. General Motors Corp.*, 812 So. 2d 296, 301 (Ala. 2001).

B. Negligence/Wantonness

***5** For a negligent failure to warn claim, a plaintiff must establish the same elements as a standard negligence action under Alabama law. *E.R. Squibb & Sons, Inc. v. Cox*, 477 So. 2d 963, 969 n.3 (Ala. 1985) (per curiam). Namely, a plaintiff must establish: "(1) that the defendant had a duty; (2) that the defendant failed to provide adequate warnings of the hazards of a particular product, thereby breaching that duty; (3) that the breach was the proximate cause of the plaintiff's harm; (4) that the plaintiff suffered injury as a result." *Bodie*, 236 Fed.Appx. at 518 (citing *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1314 (11th Cir. 2010)).

As with an AEMLD claim, "[t]he element of proximate cause is essential to the plaintiff's prima facie case of negligent failure to adequately warn. A negligent-failure-to-adequately-warn case cannot be submitted to a jury unless there is some evidence that the allegedly inadequate warning would have been read and heeded and *would have kept the accident from occurring.*" *Gurley v. Am. Honda Motor Co., Inc.*, 505 So. 2d 358, 361 (Ala. 1987) (emphasis added); *see also Clarke Indust., Inc. v. Home Indemn. Co.*, 591 So. 2d 458, 461 (Ala. 1991) ("Under both the AEMLD and the negligence theories, [the plaintiff] has the burden of proving proximate causation."). A failure-to-warn claim should not be submitted to the jury absent substantial evidence supporting proximate causation. *Barnhill v. Teva Pharms. USA, INC.*, 819 F. Supp. 2d 1254, 1262 (S.D. Ala. 2011).

To establish a claim of wantonness, "the plaintiff must prove that the defendant, with reckless indifference to the consequences, consciously and intentionally did some wrongful act or omitted some known duty. To be actionable, that act or omission *must proximately cause the injury* of which the plaintiff complains." *Norfolk S. Ry. Co. v. Johnson*, 75 So. 3d 624, 646 (Ala. 2011), *as modified on denial of reh'g* (July 8, 2011) (emphasis added) (internal citation omitted). "Proximate cause is an essential element of both negligence claims and wantonness claims." *Id.* (internal citation omitted).

C. Necessity of an Expert in Products Liability Cases to Show Medical Causation

Expert testimony is normally essential in products liability cases to establish medical causation due to the complex and technical nature of the claims. *See Emody v. Medtronic, Inc.*, 238 F. Supp. 2d 1291, 1295 (N.D. Ala. 2003) ("An essential element of all product liability cases is expert testimony, passing *Daubert* muster, that a defect was the medical cause of plaintiff's claimed injuries.") (citing *Tidwell v. Upjohn Co.*, 626 So. 2d 1297, 1299 (Ala. 1993) ("On issues of medical causation a showing of probable cause, rather than possible cause, must be made."")). As the Alabama Supreme Court explained in another products liability case,

> We recognize that *Sears, Roebuck & Co. v. Haven Hills Farm, Inc.*, supra [395 So.2d 991 (Ala. 1981)], does not stand for the proposition that expert testimony is *always* required in such cases; however, it does stand for the proposition that because of the complex and technical nature of the product and in order to present evidence from which a lay jury may reasonably infer that a defective condition of the product was the cause of the product's failure and the cause of the resultant injury to the plaintiff, expert testimony is *usually* essential and, therefore, usually required. If, however, under all the attendant circumstances, absent expert testimony, the jury could reasonably infer from the product's failure of performance that a defective condition caused the injury, a prima facie case has nonetheless been established. *Sears, Roebuck & Co. v. Haven Hills Farm, Inc.*, supra.

***6** *Brooks v. Colonial Chevrolet-Buick, Inc.*, 579 So.2d 1328, 1332 (Ala. 1991) (emphasis in original), *declined to follow on other grounds by Ex Parte General Motors Corp.*, 769 So. 2d at 903; *see also Bagley v. Mazda Motor Corp.*, 864 So. 2d 301, 313 (Ala. 2003) (requiring expert testimony to prove that the plaintiff's injury is causally related to the product's defective condition for an AEMLD claim to survive summary judgment).

Alabama expert testimony requirements in products liability actions also comport with Eleventh Circuit precedent, which dictates that in a toxic tort action, plaintiffs must prove general and specific causation through expert testimony. *McClain v. Metabolife Int'l, Inc*, 401 F.3d 1233, 1237 (11th Cir. 2005) (applying Alabama law) ("Plaintiffs must prove the toxicity of the [drug] and that it had a toxic effect on them causing the injuries that they suffered ... [t]his type of proof requires expert testimony."); *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1334 n.4 (11th Cir. 2010) (similar). Summary judgment must be granted if the nonmoving party has " 'failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof.' " *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1294 (11th Cir. 2005) (quoting *Celotex*, 477 U.S. at 323).

Here, the Court finds no basis to deviate from the general rule that expert testimony on medical causation is required. As the voluminous case docket demonstrates, a whole host of complex and technical issues have arisen throughout the course of this litigation. *See McCreeless v. Global Upholstery Co., Inc.*, 500 F. Supp. 2d 1350, 1358-59 (N.D. Ala. 2007) (Acker, J.) (similarly refusing to find an exception to the rule requiring expert testimony in a products liability action when the causation expert's opinion was excluded as unreliable). There is no dispute that Jones suffered femoral fractures. However, the fact that her femurs fractured, without any evidence as to what actually *caused* the injury, is legally insufficient.

Jones's Response to Novartis' Motion for Summary Judgment relies substantially on the opinions of two of plaintiff's proffered experts, Dr. Parisian and Dr. Hinshaw, in order to establish that there was "reasonable evidence of an association of a serious hazard with

Reclast." (Doc. 166-42 at 50). As this Court previously held, however, Dr. Parisian has been excluded from testifying to either causation or causal associations between Reclast and AFFs. (Doc. 195 at 40). Dr. Hinshaw's testimony has been excluded in full due to the flawed methodology he used in forming his opinions. *Id.* at 71. Jones's additional expert, Dr. Taylor, has also been excluded in full. *Id.* at 103. Jones's two remaining experts, Dr. Worthen and Dr. Ricketts, have been excluded from offering causation opinions. *Id.* at 118.

Without the testimony of Jones's causation experts, there is no evidence from which a jury could reasonably infer —without resorting to speculation—that Jones's Reclast injections proximately caused her fractures. *See Lowery v. Bisbee*, 623 So.2d 1047, 1049 (Ala. 1993) ("[V]erdicts may not be rested upon pure supposition or speculation, and the jury will not be permitted to merely guess as between a number of causes.") (citation omitted); *Ex parte Harold L. Martin Distributing Co., Inc.*, 769 So.2d 313, 315 (Ala. 2000) ("Alabama juries are not permitted to *speculate* as to the cause of an accident.") (emphasis in original). Novartis' Motion for Summary Judgment is due to be **GRANTED** because Jones lacks admissible expert testimony to show causation.

V. CONCLUSION

***7** Because Jones is unable to point to any admissible evidence that Reclast proximately caused her alleged injury, Novartis' Motion for Summary Judgment (doc. 106) is due to be **GRANTED**. As Novartis is entitled to judgment as a matter of law, there is no need for the Court to consider Jones's Motion for Partial Summary Judgment as to Defendant's Affirmative Defenses (doc. 110), which is due to be **TERMED** as **MOOT**. Accordingly, the hearing for oral argument on the parties' Summary Judgment Motions set for February 27, 2017, is hereby **CANCELLED**. Final Summary Judgment will be granted to Novartis by separate order.

DONE and **ORDERED** this the 10th day of February, 2017.

All Citations

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