UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN RE NUVARING® PRODUCTS LIABILITY LITIGATION	)	Case No. 4:08-MD-1964-RWS
MARIANNE PRATHER, Plaintiff	)	
v.	)	Case No. 4:08-CV-00558-RWS
ORGANON USA, INC. *et al.* Defendants.	)	

MEMORANDUM AND ORDER

Defendants in this case, hereinafter "Organon," move for summary judgment directed to Plaintiff Marianne Prather's punitive damages claim. To decide Organon's motion, I must first determine which state's law applies to this action. Applying the Second Restatement's most significant relationship test as required by Missouri's choice-of-law rules, I conclude that Missouri law applies to the punitive damages issue. To be entitled to summary judgment, Organon must show there are no genuine issues of material fact as to Prather's claim for punitive damages. Organon has not carried its burden. As a result, Organon's motion for summary judgment will be denied.

I. BACKGROUND[1]

Organon's principle place of business is in New Jersey. NuvaRing, which is manufactured, marketed, and sold by Organon, is a member of a class of prescription drugs known as combined hormonal contraceptives ("CHCs"). Unlike oral CHCs, which are taken daily, NuvaRing takes the form of a flexible ring which releases hormones over the course of treatment. The ring is vaginally inserted by women for birth control. Each month, the ring is removed and a new ring is inserted.

CHCs contain an estrogen, typically ethinyl estradiol ("EE"), and a progestin. The "generation" of CHC depends upon the type of progestin. Each "generation" of CHC typically uses the following progestins: first-generation contains norethynodrel; second-generation contains levonorgestrel; and third-generation CHCs contain desogestrel, gestodene, or norgestimate. NuvaRing uses the active metabolite of desogestrel, etonogestrel, and is therefore considered a third-generation progestin.

All CHCs can cause venous thromboembolism ("VTE"), including deep vein thrombosis ("DVT") and pulmonary embolism.[2] First-generation CHCs use high levels of EE and are associated with high incidence rates of VTE. Second-generation CHCs use a reduced amount of EE and are associated with less risk of VTE. It is generally accepted that risk of thrombosis is correlated with estrogen dose. Third-generation CHCs use lower amounts of estrogen than prior generations; however, some studies have found an increased risk of VTE with some third-generation oral CHCs as compared to second-generation oral CHCs.

[1] I am finding these facts purposes of deciding this motion only, and neither party may rely on this Order to establish any facts or defenses at trial.

[2] Venous thromboembolism is a blood clot that forms within a vein. Deep vein thrombosis is a blood clot that forms in a vein not externally visible, typically in the veins of the lower extremities. A pulmonary embolism forms when part or all of a blood clot breaks free and lodges in one of the lungs. These conditions have varying severity and can be life threatening.

Plaintiff, Marianne Prather ("Prather"), is a resident of Missouri. Organon sold and marketed NuvaRing in Missouri, which included the use of sales representatives. Dr. Evelyn Schuetz prescribed NuvaRing to Prather in Missouri, and Prather began using NuvaRing in late August 2003. At the end of September 2003, Prather began to experience leg discomfort and shortness of breath. On October 4, 2003, Prather visited the emergency room in St. Charles, Missouri, where an ultrasound revealed a deep vein thrombosis in her left leg, and a CT scan revealed multiple pulmonary emboli.

Prather claims that NuvaRing presents an undisclosed risk of VTE, including both DVT and pulmonary embolism, that is higher than second- and third-generation oral contraceptives. Prather cites evidence that progestins "counterbalance" the blood-clotting tendencies of estrogen. Prather contends that NuvaRing's use results in occasional bursts of estrogen that are unopposed by progestin, and this increases the prothrombotic propensities of NuvaRing. Prather further alleges that the progestin component of NuvaRing reaches optimum levels more slowly than the estrogen component and that this also increases the risk of blood clots. Prather alleges that Organon knew of these issues and that these properties of NuvaRing are not reflected in the drug's label and packaging inserts. Prather further alleges that Organon failed to timely disclose the occurrences of VTEs in NuvaRing clinical patients and that Organon's sales representatives misrepresent NuvaRing's hormonal "burst" propensity by telling doctors that the ring "releases a steady dose" of estrogen and progestin per day. (See Doc. 46-3, NuvaRing Sales Support, at 16).

Organon seeks summary judgment on Prather's claim for punitive damages, and Organon asserts that New Jersey law should govern the punitive damages issue. Prather contends that Missouri law controls. Organon responds that even under Missouri law, it is entitled to summary judgment.

II. DISCUSSION

A. Standard of Review

Summary judgment is proper if the evidence, viewed in the light most favorable to the nonmoving party, indicates there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Castillo v. Ridge, 445 F.3d 1057, 1060 (8th Cir. 2006) (citing Gipson v. INS, 284 F.3d 913, 916 (8th Cir. 2002)). The summary judgment rule is intended "to isolate and dispose of factually unsupported claims" and should be applied to accomplish this purpose. Celotex Corp. v. Catrett, 477 U.S. 317, 323–324 (1986). When a party moving for summary judgment points out an absence of evidence on a dispositive issue for which the nonmoving party bears the burden of proof at trial, the non-moving party must "go beyond the pleadings and by [his] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." Id. at 324–25 (internal quotations and citation omitted). Thereafter, summary judgment is mandated against the non-moving party who fails to make a showing sufficient to establish a genuine issue of fact for trial. Id. at 322, 324–25. The party opposing a motion for summary judgment must rely on more than conclusory statements or allegations unsupported by facts. Davis v. U.S. Bancorp, 383 F.3d 761, 765 (8th Cir. 2004) (citation omitted). In ruling on a motion for summary judgment, a court must consider all inferences drawn from the underlying facts in a light most favorable to the party opposing the motion and resolve all reasonable doubts against the moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Summary judgment is not proper if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Id. at 248.

B. Choice of Law for Punitive Damages

As a threshold matter, the parties in this case dispute whether the law of Missouri or New Jersey should be applied to Prather's claim for punitive damages. Neither party contests that the respective laws conflict.[3] A district court sitting in diversity must apply the choice-of-law rules of the state in which the action was originally filed. Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496 (1941); Wolfley v. Solectron USA, Inc., 541 F.3d 819, 823 (8th Cir. 2008). When determining choice-of-law issues, Missouri courts apply the "most significant relationship" test established by the Restatement (Second) of Conflicts of Law. Kennedy v. Dixon, 439 S.W.2d 173, 184 (Mo. banc 1969). This test is applied individually to each particular issue under the principle of "dépeçage." See Glasscock v. Miller, 720 S.W.2d 771, 775 (Mo. Ct. App. 1986).

To determine whether a state has a more significant interest than the state of injury, Missouri courts apply Restatement (Second) Section 145, which provides two sets of criteria for determining the state with the most significant relationship. Natalini v. Little, 185 S.W.3d 239, 248–50 (Mo. Ct. App. 2006); Goede v. Aerojet General Corp., 143 S.W.3d 14, 25 nn.7 & 8, 26 (Mo. Ct. App. 2004) (abrogated on other ground by Sanders v. Ahmed, 364 S.W.3d 195, 207 (Mo. banc 2012). First, courts must consider whether a state has a more significant interest under the principles stated in Restatement (Second) Section 6, which include:

(a) the needs of the interstate and international systems;

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[3] In Missouri, awards of punitive damages are limited to the greater of $500,000 or five times the net amount of the judgment awarded plaintiff against the defendant. R.S. Mo. § 510.265.1 (2005). In contrast, New Jersey law provides:

> Punitive damages shall not be awarded if a drug or device . . . which caused the claimant's harm was subject to premarket approval . . . by the federal Food and Drug Administration . . . and was approved . . . . However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded.

N.J. Stat. Ann. § 2A:58C–5c (1995).

(b) the relevant policies of the forum;

(c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue;

(d) the protection of justified expectations;

(e) the basic policies underlying the particular field of law;

(f) certainty, predictability and uniformity of result; and

(g) the ease in the determination and application of the law to be applied.

Restatement (Second) § 6 (1971).

Second, Section 145 requires that courts must consider the following contacts when applying the Section 6 principles: (1) the place of the injury; (2) the place of misconduct; (3) the domicile, residence, nationality, place of incorporation, and place of business of the parties; and (4) the place where the relationship between the parties is centered. Id. § 145(2). The number of contacts favoring a particular state plays little importance; rather, Missouri courts "evaluate the contacts based on their relative importance to the particular issue." Goede, 143 S.W.3d at 26 (citing Dillard v. Shaughnessy, Fickel & Scott Architects, Inc., 943 S.W.2d 711, 715 (Mo. Ct. App. 1997)). Thus, under Missouri's choice-of-law rules, the law of the state with the most significant relationship to the punitive damages issue will govern Prather's claim for punitive damages.

Section 146 of the Restatement applies to actions for personal injury and calls for states to apply the substantive law of the "state where the injury occurred" unless, "with respect to the particular issue[,] some other state has a more significant relationship" to the parties and occurrences under the principles listed in Section 6. Restatement (Second) § 146. With respect to the issue of damages, Restatement Section 171 provides that the state selected by Section 145

determines the measure of damages. Restatement (Second) § 171; see also id. at cmt. d ("The law selected by application of the rule of § 145 determines the right to exemplary damages."). Section 145 requires an analysis into the purpose of the issue. Where, as with punitive damages, the primary purpose of the rule involved is to deter or punish misconduct, the place where the conduct occurred has particular significance. See Restatement (Second) § 145 cmt. e; see also Bradshaw v. Deming, 837 S.W.2d 592, 594 (Mo. Ct. App. 1992) ("Punitive damages . . . have as their purpose, not the compensation of the plaintiff, but the punishment of the defendant and the deterrence of the offending conduct in the future.").

1) Relevant Contacts under Restatement § 145(2)

a) Place of Injury

Both parties agree that Missouri is the state of the alleged injury. Organon argues, however, that because the place of injury is merely "fortuitous," it should be afforded little weight. It has been held that "[w]here a party is domiciled in the place of injury, purchases the allegedly defective product there, and uses it only there, the place of injury is not fortuitous." Yocham v. Novartis Pharmaceuticals Corp., 736 F. Supp. 2d 875, 882 (D.N.J. 2010). The Restatement provides an example of a fortuitous injury: a plaintiff purchases an airline ticket in one state to fly to another state, and the airplane crashes in a third state. See Restatement (Second) § 146 cmt. d. In such a case, the place of injury "bears little relation to the occurrence and the parties" and the defendant would have no reason to foresee that the injury would occur in the particular state. See Restatement (Second) § 145 cmt. e. This is not a case where a plaintiff purchased a product and then travelled into a new, unforeseen jurisdiction when calamity struck. Organon marketed and sold NuvaRing in Missouri, where Prather purchased and used it. Prather

suffered her DVT and pulmonary emboli in Missouri. The place of injury is not fortuitous as that term is used in the choice-of-law analysis.

b) Place of Misconduct

The state in which the misconduct occurs is the contact that bears the most significance to the issue of punitive damages. See Restatement (Second) § 145 cmt. c. Organon argues that the majority of the relevant conduct occurred in New Jersey because that state was Organon's point of contact with the FDA. Prather responds that the relevant conduct occurred in Missouri, as Organon employed sales representatives in Missouri who, when promoting NuvaRing, allegedly failed to warn Prather's physician of NuvaRing's dangers. Prather has the better argument. "[T]he conduct causing injury in a prescription drug products liability case, including failure to warn and warranty cases, occurs primarily where the injured party was prescribed and ingested the drug." Yocham, 736 F. Supp. 2d at 882 (citing Montgomery v. Wyeth, 540 F. Supp. 2d 933, 944 (E.D. Tenn. 2008); Bearden v. Wyeth, 482 F. Supp. 2d 614, 620 (E.D. Pa. 2006); Cornett v. Johnson & Johnson, 998 A.2d 543, 551–52 (N.J. Super. App. Div. 2010)). I find that the majority of the misconduct occurred in Missouri.[4]

c) Domicile of the Parties

Prather is a Missouri resident. Organon's principle place of business in the United States is New Jersey. Because Prather is from Missouri and Organon is from New Jersey, this factor has a neutral effect on the choice-of-law analysis.

d) Place Where the Relationship Between the Parties Is Centered

[4] The parties allude to the possibility that some decisions by Organon may have been made in either the Netherlands or Germany. If so, this would merely dilute Organon's argument that New Jersey bears the most significant relationship. The parties fail to adequately support this premise in the record.

Missouri is the place at which the parties' relationship centers, as their relationship arises solely through this litigation. See Cornett, 998 A.2d at 552 (placing locus of relationship in state where patient and doctors received warnings or suffered from their absence). This contact, however, has little significance to the choice of law analysis here. See Chicago, 644 F.2d at 612 n.20 (noting contact's significance primarily derives from interest in regulating conduct).

2) Section 6 Principles

The second step of the Restatement analysis is to apply the principles enumerated in Section 6 of the Restatement and thereby determine whether Missouri, as the state of injury, plaintiff's domicile, locus of the parties' relationship, and the site of much of the alleged misconduct, retains a greater significance than New Jersey, the state of Organon's principle business and the state in which some misconduct allegedly occurred.

Organon argues that the "justified expectations" of the parties weighs in favor of New Jersey law. However, "the protection of the justified expectations of the parties, which is of extreme importance in such fields as contracts, property, wills and trusts, is of lesser importance in the field of torts[;] . . . persons who cause injury . . . unintentionally . . . usually act without giving thought to the law that may be applied . . . ." Restatement (Second) cmt. b. Similarly, "the values of certainty, predictability and uniformity of result are of lesser importance in torts" than in areas like contracts or estates where the parties are likely to plan their transactions in accordance with applicable law. See id. Moreover, Missouri's status as the locus of the parties' relationship militates against Organon's claim that it justifiably expected New Jersey law would govern Missouri NuvaRing claims. Organon sold and marketed NuvaRing in Missouri. In doing so, Organon should have expected to be subjected to Missouri law regulating such conduct.

Organon argues that applying New Jersey law would simplify the determination and application of a punitive damages analysis. It bases this argument upon a ruling by that state's courts that essentially bars all punitive damages in pharmaceutical cases where the FDA approves the label. See, e.g., McDarby v. Merck & Co., Inc, 949 A.2d 223, 276 (N.J. Super. App. Div. 2008) (finding exception preempted by Federal Food Drug and Cosmetic Act). However, federal courts are not bound by state court rulings on preemption. See Casey v. FDIC, 583 F.3d 586, 592 (8th Cir. 2009). Moreover, federal courts have reached differing conclusions on the preemption issue. See Zimmerman v. Novartis Pharm. Corp., 889 F. Supp. 2d 727, 767–68 (D. Md. 2012) (discussing divergence). Contrary to Organon's argument, I find that applying New Jersey law to punitive damages would entail more difficulty in applying the law.

An analysis of the states' interests does not yield a result favoring New Jersey law. New Jersey adopted its products liability law in order to "limit[] the liability of manufacturers of FDA-approved products by reducing the burden placed on them by product liability litigation." Rowe v. Hoffman-La Roche, Inc., 917 A.2d 767, 774 (N.J. 2007). In doing so, the New Jersey legislature "balanced the need to protect individuals against the need to protect an industry with a significant relationship to [its] economy and public health." Id. Missouri allows punitive damages in order to punish and deter similar conduct. See Vaughan v. Taft Broadcasting Co., 708 S.W.2d 656, 660 (Mo. banc 1986). Moreover, Missouri presumably considered the effect that its laws would have upon its own economy when it placed limits upon the amount of punitive damages. This case presents a true conflict of laws, because both New Jersey and Missouri have interests that would be furthered by applying their respective statutes to Prather's claim.

While New Jersey has an interest in protecting its corporations from the burdens of frivolous lawsuits, that interest is diminished where the defendant corporation's conduct occurs outside the state. Cf. Rowe, 917 A.2d at 629 ("To allow a life-long Michigan resident who received an FDA-approved drug in Michigan and alleges injuries sustained in Michigan to by-pass his own state's law . . . overvalu[es] [New Jersey's] true interest in this litigation."). Organon allegedly engaged in misconduct in Missouri and in doing so injured a Missouri citizen in Missouri. Having considered the principles set forth in Section 6, I find that Missouri has the most significant relationship to the parties and occurrences. Missouri law will govern punitive damages.

C. Motion for Summary Judgment

Organon contends it is entitled to summary judgment as a matter of Missouri law on the issue of punitive damages. In a negligence action, punitive damages may be awarded if the defendant knew or had reason to know a high degree of probability existed that the action would result in injury. Stojkovic v. Weller, 802 S.W.2d 152, 155 (Mo. banc 1991), overruled on other grounds by Rodriguez v. Suzuki Motor Corp., 936 S.W.2d 104 (Mo. banc 1996); Hoover's Dairy, Inc. v. Mid–America Dairymen Inc., 700 S.W.2d 426, 436 (Mo. banc 1985). Similarly, in a strict liability case, punitive damages may be awarded if a plaintiff presents evidence that the defendant placed in commerce an unreasonably dangerous product with actual knowledge of the product's defect. Letz v. Turbomeca Engine Corp., 975 S.W.2d 155, 164–65 (Mo. Ct. App. 1997) (citing Sparks v. Consolidated Aluminum Co., 679 S.W.2d 348, 354 (Mo. Ct. App. 1984)). Under both negligence and strict liability theories, a plaintiff must also show that the defendant exhibited a complete indifference to or conscious disregard for the safety of others in order to recover punitive damages. Id.

Organon presents one argument in support of its motion for summary judgment under Missouri law.[5] Organon asserts that its warnings preclude a finding of conscious disregard towards the risk of VTE and pulmonary embolism that NuvaRing presents.

A "specific and explicit" warning of the defective condition can negate the inference of a defendant's indifference to consumer safety. Drabik v. Stanley-Bostich Inc., 997 F.2d 496, 510 (8th Cir. 1993); see also Jone v. Coleman Corp., 183 S.W.3d 600, 610 (Mo. Ct. App. 2005) (finding warning that "burning products consume oxygen" and "ample ventilation must be provided" negated conscious disregard of safety towards carbon monoxide danger).

Organon argues that its warnings explicitly state that there is a risk of pulmonary embolism and VTE associated with all hormonal contraceptives, including NuvaRing. However, the issue here is not whether the label warns of the risk of VTE and pulmonary embolism presented by NuvaRing. Rather, the issue is whether the label warns of the *difference in risk* of those conditions between NuvaRing and second- and third-generation oral contraceptives.

The NuvaRing label prominently addresses the risk differential of VTE:

> Several epidemiology studies indicate that third generation *oral* contraceptives, including those containing desogestrel (etonogestrel, the progestin in NuvaRing, is the biologically active metabolite of desogestrel), are associated with a higher risk of venous thromboembolism than certain second generation *oral* contraceptives. In general, these studies indicate an approximate two-fold increased risk, which corresponds to an additional one or two cases of venous thromboembolism per 10,000 women-years of use. However, data from additional studies have not shown this two-fold increase in risk. *It is unknown if NuvaRing has a different risk of venous thromboembolism than second generation oral contraceptives.*

[5] Organon also makes a one-sentence argument that punitive damages should be foreclosed, because Prather's causation expert, Dr. Richart, conceded that no data exist to show a difference in risk between NuvaRing and second-generation pills. However, Dr. Richart cites in his supplementary affidavit an epidemiological study that links NuvaRing specifically to an increased risk of VTE. (Doc. 37-2 ¶ 10). This argument, therefore, fails.

(Doc. 32-1, NuvaRing Approved Label) (emphasis added). NuvaRing's Patient Information section similarly states: "The risk of getting blood clots may be greater with the type of progestin in NuvaRing than with some other progestins in certain low-dose birth control pills. It is unknown if the risk of blood clots is different with NuvaRing use than with the use of certain birth control pills." (Id.). The NuvaRing label also states that "[t]here is no epidemiologic data available to determine whether safety and efficacy with the vaginal route of administration of combination hormonal contraceptives would be different from the oral route." (Id.).

The uncertainty inherent to NuvaRing's warnings is made apparent by the effect they had on Prather and her prescribing physician, Dr. Schuetz. Dr. Schuetz testified that, after reading the NuvaRing label, she did not "have an understanding that NuvaRing had hormonal ingredients in it that had a higher risk of causing blood clots than other birth control products." (Doc. 42-5, Schuetz Dep., at 113; id. at 127 ("I did not perceive that as a different—difference in risk.")). Similarly, Prather stated that, after reading the patient information section of the NuvaRing label, she did not understand that NuvaRing was associated with an increased risk of blood clots, including pulmonary embolism. (Doc. 42-6, Prather Dep. at 166).[6]

The cases cited by Organon are distinguishable from the one at bar. In those cases, the warning specifically listed known risks for the product upon which they appeared. See Jone, 183 S.W.3d at 610–11 (warning on propane lantern fuel canister stated "all burning products consume oxygen"); Scharff v. Wyeth, No. 2:10-CV-220-WKW, 2012 WL 3149248, at *9 & n.12 (M.D. Ala. Aug. 1, 2012) (warning on estrogen replacement drug stated that estrogen replacement drugs can increase risk of breast cancer); Salvio v. Amgen, Inc., No. 2:11-CV-00553, 2012 WL 627446, at *8 (W.D. Pa. Feb. 15, 2012) ("[S]erious infections and sepsis,

[6] This statement occurred as part of the deposition's errata and corrects Prather's previous contradictory statement. For the purposes of this motion, she is entitled to all favorable inferences.

including fatalities, have been reported with the use of Enbrel."). Not only did the NuvaRing warning address oral contraceptives—a different pharmaceutical product—but the warning explicitly stated that it was unknown whether increased risks intrinsic to those products could be attributed to NuvaRing. Rather than evidencing care towards consumers, when read in the light most favorable to Prather, the NuvaRing label exhibits agnosticism.

After considering the testimony of Dr. Schuetz and Prather and the plain language of NuvaRing's label, I cannot find as a matter of law that the NuvaRing label specifically and explicitly warns of the difference in risk of VTE and pulmonary embolism such that punitive damages should be foreclosed. Organon fails to carry its burden to show it is entitled to summary judgment as is required by Celotex. 477 U.S at 324–25. I will, therefore, deny Organon's motion for summary judgment regarding punitive damages.

III. CONCLUSION

For the foregoing reasons, I find that Missouri law controls the issue of punitive damages. I also find that the NuvaRing label does not foreclose punitive damages as a matter of law.

Accordingly,

IT IS HEREBY ORDERED that Organon's motion for summary judgment directed to plaintiff's punitive damages claim (Doc. 24) is **DENIED**.

RODNEY W. SIPPEL
UNITED STATES DISTRICT JUDGE

Dated this 12th day of July, 2013.