

**FILED**

**MAY 03 2013**

**BRIAN R. MARTINOTTI, J.S.C.**

This Order has been prepared and filed by the Court.

**IN RE NUVARING® LITIGATION**

SUPERIOR COURT OF NEW  
JERSEY

LAW DIVISION

BERGEN COUNTY

DOCKET NO. BER-L-3081-09

CIVIL ACTION

**ORDER**

*THIS MATTER* having been opened to the Court on motion by defendants Organon USA Inc., Organon Pharmaceuticals USA Inc., Organon International Inc., and Merck & Co., Inc. (f/k/a Schering-Plough Corporation) (“Defendants”) to grant summary judgment in their favor on the issue of all plaintiffs’ punitive damages claims; the Court having considered the moving papers, opposition thereto and the argument of counsel; and good cause having been shown;

For the reasons set forth in the accompanying opinion;

*IT IS* on this 3rd day of May 2013,

**ORDERED:**

1. Defendants’ motion for summary judgment on the issue of punitive damages is DENIED without prejudice.

2. Defendants' motion to apply New Jersey law to the issue of New Jersey punitive damages is denied. The law of Plaintiffs' individual states should be applied at the time of a subsequent summary judgment motion or trial.
3. A copy of this Order shall be served on all counsel within seven (7) days and posted on the court's website.

A handwritten signature in black ink, appearing to read 'B. R. Martinotti', written over a horizontal line.

BRIAN R. MARTINOTTI, J.S.C.

**IN RE NUVARING® LITIGATION**

SUPERIOR COURT OF NEW JERSEY

LAW DIVISION

BERGEN COUNTY

DOCKET NO. BER-L-3081-09

CIVIL ACTION

Argued: March 4-5, 2013 (Decision Reserved)  
Transcript Received: March 19, 2013  
Decided: May 3, 2013

Michael T. Scott, for defendants (Reed Smith, LLP, attorneys).

Hunter Shkolnik, for plaintiffs (Napoli Bern Ripka Shkolnik & Associates, attorneys).

**MARTINOTTI, J.S.C.**

Before this Court is a motion by defendants Organon USA Inc., Organon Pharmaceuticals USA Inc., Organon International Inc., and Merck & Co., Inc. (f/k/a Schering-Plough Corporation) (“Defendants”) for summary judgment on the issue of punitive damages for all plaintiffs (“Plaintiffs”) in this litigation. This motion was opposed by the Plaintiffs.

**BACKGROUND/FACTS**<sup>1</sup>

Submitted with this motion were nine<sup>2</sup> individual summary judgment motions by Defendants in the Group I bellwether cases. Oral argument was heard on those motions

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<sup>1</sup> The facts are limited to those material to the instant motion. This matter was assigned to this Court for centralized management (now multicounty litigation) in March 2009. There have been 197 cases filed. For an overview of underlying facts, see the New Jersey Judiciary Multicounty litigation Center website, <http://www.judiciary.state.nj.us/mass-tort/nuvaring/index.htm>. For a recitation of the applicable facts, see this Court’s decision in the associated summary judgment motions.

and this punitive damages motion on March 4 and 5, 2013. The Court granted summary judgment in favor of the Defendants on April 18, 2013, based on adequacy of the warning in Bozicev and Mariconda, and based on breach of express warranties and causation in all Group I cases. In the cases of Barrow, Fields, Wilson-Johnson, Namack, and Ziwange, the Court found that, under those states' laws, there were material issues of fact as to the adequacy of the label.

On April 29, 2013, a telephone conference was held in which counsel agreed that the issue of punitive damages was still pending as to the cases remaining in the litigation.<sup>3</sup> Counsel for Plaintiffs also discussed the possibility of new discovery in the New Jersey MDL cases which would prevent a finding similar to that of Bozicev and Mariconda. For this reason, and because the Court found that material issues of fact existed as to adequacy of the label under certain states' laws in the summary judgment decision, this opinion decides only which state's punitive damages law applies. It does not reach the issue of whether punitive damages can ultimately be awarded under the governing law, as that decision would require an analysis of that state's law and a finding as to defendants' conduct under that law.

## **ARGUMENTS**

### **I. Defendants' Argument**

Defendants argue that New Jersey law applies to all cases under New Jersey's choice-of-law principles – specifically, the “most significant relationship” test. Accordingly, Defendants apply the New Jersey Product Liability Act (“PLA”), N.J.S.A. §

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<sup>2</sup> Counsel agreed on January 28, 2013, to the dismissal, with prejudice, of two Group I bellwether cases: Medina (BER-L-2680-09) and Kippola (BER-L-2705-09).

<sup>3</sup> This decision was completed on May 2, 2013, to be entered on May 3, 2013. On the morning of May 3, the Court received Plaintiffs' request via email to hold the decision until the Group II cases have been briefed. Defendants opposed Plaintiffs' request.

2A: 58C-5(c), which states that punitive damages may not be awarded in prescription drug cases. Although the PLA provides an exception where manufacturers may be liable for punitive damages where it “knowingly withheld or misrepresented information required to be submitted under the agency’s regulations,” Defendants argue that this exception is preempted because it would require proof of fraud on the FDA, which the FDA has the sole authority to regulate. (Defs.’ Mot. 16. (citing McDarby v. Merck & Co., 401 N.J. Super. 10, 94, 949 A.2d 223 (App. Div. 2008); Buckman Co. v. Plaintiffs’ Legal Committee, 531 U.S. 341, 121 S. Ct. 1012 (2001))). Defendants consequently argue that, based on the FDA’s approval of their label, punitive damages are not permissible in these cases.

Alternatively, Defendants argue that, even if the exception in the PLA is not preempted by the FDA’s authority, Plaintiffs have not demonstrated a material issue of fact to show that Defendants knowingly withheld or misrepresented information required under the FDA.

## **II. Plaintiffs’ Argument**

Plaintiffs argue that, as an initial matter, New Jersey’s PLA is not applicable to all cases under New Jersey’s “most significant relationship” test. Additionally, Plaintiffs assert that, under Rule 4:46, Defendants should have submitted individual punitive damages motions for each case, and that Defendants conceded that the laws of each state apply because they proceeded in that same manner in the liability portions of summary judgment cases.

Alternatively, Plaintiffs argue that, even if New Jersey’s PLA applies to all cases, the PLA’s exception is not preempted by the FDA’s regulations as stated in McDarby.

Plaintiffs cite to several courts, notably the District Court of New Jersey, and the Eastern Districts of New York, Pennsylvania, and California, which express concern over the viability of McDarby after the Supreme Court in Levine v. Wyeth, 555 U.S. 555, 129 S. Ct. 1187 (2009), held that they “could discern no congressional intent to vest the FDA with the sole authority to ensure drug safety and effectiveness.”<sup>4</sup>

In applying New Jersey’s law, Plaintiffs also raise the Punitive Damages Act, N.J.S.A. § 2A:15-5.12(a), which states that punitive damages are only permissible if, by clear and convincing evidence, the plaintiff proves causation and that “such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions.”

To satisfy this standard, Plaintiffs assert that they have been able to show that material issues of fact exist as to the willfulness of Defendants actions. Plaintiffs argue that Defendants had evidence of an increased risk that they consciously disregarded when marketing the product to physicians and customers, and have provided to the Court internal communications by the Defendants attempting to remove the existence of the VTEs from the labels. (See Pls.’ Opp. 40, Ex. HH (“My major comment on the US [Package Insert (“PI”)] relates to including the one case of thrombosis. We should really try to get it out of the text.”); Ex. II (“Or could we use [the animal studies] as a bargaining chip for other, more important issues such as the VTE warning, bleeding data, etc?”); Ex. GG (“I have reviewed the new proposal of the NuvaRing PI made by the

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<sup>4</sup> Significantly, Plaintiffs do not address how, if the PLA is not preempted, the Court should overcome the exception within the PLA requiring that the manufacturer “knowingly withheld or misrepresented information required to be submitted under the agency’s regulations” in order to find punitive damages. N.J.S.A. § 2A: 58C-5c (emphasis added).

FDA. To my satisfaction a number of the critical issues have been implemented in the current proposal (e.g. the deletion of the single VTE case”).

Additionally, Plaintiffs argue that the label is inaccurate on its face. Specifically, Plaintiffs point out that the label incorrectly states that “[i]t is unknown if NuvaRing has a different risk of [VTE] than second generation oral contraceptives,” because Defendants have conceded that third generation contraceptives, of which NuvaRing® is one, has a higher risk than second generation contraceptives. Finally, Plaintiffs assert, through expert testimony, that the additional VTEs discovered in clinical trials (one prior to FDA approval of the label and three after) indicate an increased risk of which Defendants should have been aware.

## **DECISION**

### **I. Summary Judgment**

Under the developed governing standard, a summary judgment motion requires “searching review” of the record on the part of the trial court to ascertain whether there is a genuine issue of material fact. R. 4:46-2. Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 541, 666 A.2d 146 (1995). As such, the court must “consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational fact finder to resolve the alleged disputed issue in favor of the non-moving party.” Id. at 540. Summary judgment must be granted when the evidence “is so one-sided that one party must prevail as a matter of law.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 106 S. Ct. 2505, 2512, 91 L. Ed. 2d 202, 214 (1986). This means that summary judgment cannot be defeated if the non-moving party does not “offer[] any concrete evidence from which a reasonable juror

could return a verdict in his favor.” Id. at 256, 106 S. Ct. at 2514, 91 L. Ed. 2d at 217.

The non-movant has the “burden of producing in turn evidence that would support a jury verdict,” and must “set forth specific facts showing that there is a genuine issue for trial.”

Id. at 256; 106 S. Ct. at 2514; 91 L. Ed. 2d at 217.

“[C]onclusory and self-serving assertions” in certifications without explanatory or supporting facts will not defeat a meritorious motion for summary judgment. Puder v. Buechel, 183 N.J. 428, 440, 874 A.2d 534 (2005) (citing Martin v. Rutgers Cas. Ins. Co., 346 N.J. Super. 320, 323, 787 A.2d 948 (App. Div. 1999)). Competent opposition requires “competent evidential material” beyond mere “speculation” and “fanciful arguments.” Merchs. Express Money Order Co. v. Sun Nat’l Bank, 374 N.J. Super. 556, 563, 866 A.2d 189 (App. Div. 2005), appeal dismissed, 183 N.J. 592 (2006); O’Loughlin v. Nat’l Cmty. Bank, 338 N.J. Super. 592, 606-07, 770 A.2d 1185 (App. Div.) (opponent must do more than establish abstract doubt regarding material facts), certif. denied, 169 N.J. 606 (2001). See also James Talcott, Inc. v. Shulman, 82 N.J. Super. 438, 443, 198 A.2d 98 (App. Div. 1964) (“Mere sworn conclusions of ultimate facts, without material basis or supporting affidavits by persons having actual knowledge of the facts, are insufficient to withstand a motion for summary judgment.”).

## **II. Choice Of Law**

A lawsuit filed in New Jersey is subject to New Jersey’s choice-of-law rules. Erny v. Estate of Merola, 171 N.J. 86, 94, 792 A.2d 1208 (2002). The Court must conduct a choice of law analysis “(1) when the case is connected with more than one state, and . . . (2) when the laws of the involved states differ on the point in issue.” Pfizer, Inc. v. Emp’rs Ins. Of Wausau, 154 N.J. 187, 199, 712 A.2d 634 (1998) (internal

quotation marks omitted). “Th[is] is done by examining the substance of the potentially applicable laws to determine whether there is a distinction between them.” P.V. v. Camp Jaycee, 197 N.J. 132, 143, 962 A.2d 453 (2008) (internal quotation marks omitted). The Court concludes that, based on the parties’ opposing positions on the issue of which state’s law should apply, New Jersey’s law regarding punitive damages conflicts with the laws of each plaintiff’s state.

Because a conflict exists, the Court must look to New Jersey’s choice-of-law rules – that is, the most significant relationship test. Camp Jaycee, supra, 197 N.J. at 142-43, 962 A.2d 453 (holding that the most significant relationship test from Restatement (Second) of Conflict of Laws § 146 (1971) (“Restatement (Second)”) applies to torts actions). This “most significant relationship” standard generally requires application of “the law of the state of the injury . . . unless another state has a more significant relationship to the parties and issues.” Camp Jaycee, supra, 197 N.J. at 143, 962 A.2d 453.

To determine whether a state has a more significant relationship, the Court must examine the factors set forth in § 145 of Restatement (Second): “(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered.”

Restatement (Second) § 145; accord Camp Jaycee, supra, 197 N.J. at 142-43, 962 A.2d 453. These contacts should be viewed in light of the principles set forth in § 6 of

Restatement (Second):

- (a) the needs of the interstate and international systems,
- (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) ease in the determination and application of the law to be applied.

[Restatement (Second) § 6 (2); accord Camp Jaycee, supra, 197 N.J. at 147; Erny, supra, 171 N.J. at 101-02, 792 A.2d 1208.]

## **A. Restatement (Second) § 145**

### **i. Where The Injury Occurred**

The first factor is the place where the injury occurred. Each injury occurred in the Plaintiff's respective "home" state. This provides a presumption that those states' laws apply, unless the law of another state has a more significant relationship. Camp Jaycee, supra, 197 N.J. at 144, 962 A.2d 453. Importantly, the Supreme Court in Camp Jaycee stated, "Section 146 recognizes the intuitively correct principle that the state in which the injury occurs is likely to have the predominant, if not exclusive, relationship to the parties and issues in the litigation." Id. See Cornett v. Johnson & Johnson, 414 N.J. Super. 365, 379-80, 998 A.2d 543 (App. Div. 2010) (finding that the state of plaintiff's residency was the place where the injury occurred because plaintiffs received all medical care there and that is where "the stent was purchased, implanted, and allegedly became blocked") (citing Rowe v. Hoffman La-Roche, Inc., 189 N.J. 615, 629, 917 A.2d 767 (2007)); Yocham v. Novartis Pharms. Corp., 736 F. Supp. 2d 875, 882 (D.N.J. 2010) (finding that plaintiff's injury occurred in her home state because she "purchase[d] the allegedly defective product there, and use[d] it only there"); Millian v. Organon USA, Inc., Dkt. No. BER-L-

2849-09 (Law Div. March 15, 2011) (finding that injury occurred in plaintiff's state of residency where she obtained and used NuvaRing®), aff'd, Dkt. A4115-10T2 (App. Div. Aug. 1, 2012), available at <http://njlaw.rutgers.edu/collections/courts/appellate/a4115-10.opn.html>.

Defendants argue that this factor is insignificant and that the place of plaintiffs' injuries is fortuitous. Despite Defendants' argument, the Court does not find that this factor is a fortuity. The Supreme Court in Camp Jaycee noted that "[t]he place of injury is fortuitous when 'it bears little relation to the occurrence and the parties with respect to the particular issue.'" Camp Jaycee, supra, 197 N.J. at 146, 962 A.2d 453 (quoting Restatement (Second) § 145 comment e). Defendants concede that its conduct is "at the heart of punitive damages allegations" (Mot. 7; see Transcript of Hearings, dated March 5, 2013, at 87:2-4), and as the Court will explain infra Part II(A)(ii), the more relevant conduct occurred in each plaintiff's state. See Yocham, supra, 736 F. Supp. 2d at 882.<sup>5</sup> Where the injury and the conduct occur in the same state, the law of that state will be applied, "subject only to rare exceptions." Restatement (Second) § 145, comment d; Camp Jaycee, supra, 197 N.J. at 144, 962 A.2d 453. The Court finds no exceptions that would allow this factor to be "discounted as a fortuity." Cornett, 414 N.J. Super. at 379, 998 A.2d 543 (finding that plaintiff's state of residence had the most significant relationship to the case because the medical device was purchased and implanted there and the injury occurred there, such that the plaintiff "was neither operated on nor injured

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<sup>5</sup> Defendants also disagree with Yocham on this point, arguing that the court presumed the injury and conduct occurred in the same state (Defs.' Reply 5), but the Court is persuaded by Yocham because the court acknowledged that the conduct occurred in more than one location while finding that conduct allegedly causing the injury – i.e. failing to adequately warn – occurred in plaintiff's state. Yocham, supra, 736 F. Supp. 2d at 882.

in [that state] by pure ‘happen-stance’ ”). Therefore, as this Court concluded in Millian, the Court finds that the injury occurred in each plaintiff’s home state.

**ii. Where The Injury-Causing Conduct Occurred**

The second factor is determining where the conduct causing Plaintiffs’ injuries took place. “[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, supra, 736 F. Supp. 2d at 882 (citing Cornett, supra, 414 N.J. Super. 365, 998 A.2d 543). As in Yocham, plaintiffs allegedly failed to receive the adequate warnings in each plaintiff’s home state, and plaintiffs “ingested the drug that allegedly caused [their] injur[ies] in [those states].” Id. at 882. The court acknowledges that the product and label were submitted to the FDA for approval and subsequently distributed from Defendants’ New Jersey headquarters, “[b]ut the more relevant conduct at issue is what Defendant revealed to Plaintiff and her doctor about the drug, conduct which occurred, if at all, in [each plaintiff’s state].” Id.

**iii. Domicil, Residence, Nationality, Place Of Incorporation And Place Of Business Of The Parties**

Regarding this third factor, Plaintiffs are undoubtedly domiciled in their respective states. With respect to corporations such as Defendants, the court in Camp Jaycee stated:

Courts should focus not only on an entity's place of incorporation but also on its principal place of business. Indeed, in balancing those two epicenters, “[a]t least with respect to most issues, a corporation's principal place of business is a more important contact than the place of incorporation, and this is particularly true in situations where the corporation does little, or no, business in the latter place.”

[Camp Jaycee, *supra*, 197 N.J. at 146, 962 A.2d 453 (quoting Restatement (Second) § 145, comment e).]

Defendant Organon is incorporated in Delaware, and Defendants Schering-Plough and Merck are incorporated in New Jersey. All have their principal place of business in New Jersey. The parties stipulate, and the Court agrees, that this factor is neutral because Plaintiffs are from their respective states and Defendants principal place of business is in New Jersey.

#### **iv. Where The Relationship Between The Parties Is Centered**

The last factor is “the place where the relationship, if any, between the parties is centered.” Several courts have found that the parties’ relationship is centered where plaintiffs “received [warnings] or suffered from their omission,” despite the warnings being issued from another state. Cornett, *supra*, 414 N.J. Super. at 380, 998 A.2d 543; Yocham, *supra*, 736 F. Supp. 2d at 882 (finding that the relationship occurred in plaintiff’s state even though defendant’s conduct arguably had contacts with both states); Bearden v. Wyeth, 482 F. Supp. 2d 614, 620 (E.D. Pa. 2006) (“[T]he parties’ relationship was centered in decedent’s home state, where he purchased, ingested and allegedly was injured by [the drug].”).<sup>6</sup>

#### **B. Restatement (Second) § 6**

The final step in New Jersey’s conflict-of-laws analysis is to review the factors set forth in section 6. “Reduced to their essence, the § 6 principles are: ‘(1) the interests of interstate comity; (2) the interests of the parties; (3) the interests underlying the field of

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<sup>6</sup> The Court is persuaded by Cornett, Yocham, and Bearden based on the Court’s finding that the injury-causing conduct is primarily based in plaintiffs’ respective states. See *supra* Part II(A)(ii); cf. Irby v. Novartis Pharms. Corp., Nos. MID-L-1815-08, 278, 2011 WL 5835414 (N.J. Super. Nov. 18, 2011) (finding the party’s relationship to be based in New Jersey because defendant’s relevant conduct was also based there).

tort law; (4) the interests of judicial administration; and (5) the competing interests of the states.’ ” Camp Jaycee, supra, 197 N.J. at 147, 962 A.2d 453 (quoting Erny, supra, 171 N.J. at 101-02, 792 A.2d 1208).

Some cases, such as Camp Jaycee, analyze each factor, finding that the state where the injury and conduct occurred has the most significant relationship with the case. See Camp Jaycee, supra, 197 N.J. at 153, 962 A.2d 453 (finding that New Jersey has “continuously deferred to the rights of other jurisdictions to regulate conduct within their borders”).

Several decisions have applied these factors generally, without examining each factor individually, finding that they warrant application of another state’s law. Yocham, supra, 736 F. Supp. 2d at 882 (“Returning to the ultimate question of the significance of the states’ relations to the parties and events in light of the principles contained in § 6 of the Restatement, it is clear that Texas has the more significant relationship.”) (citing Rowe, supra, 189 N.J. at 629, 917 A.2d 767); Cornett, supra, 414 N.J. Super. at 379, 998 A.2d 543 (“[T]he factors of Section 145 of the Restatement, when assessed in terms of the standards of Section 6, show that Kentucky had the more significant relationship to this case.”). For example, in Erny, supra, 171 N.J. at 101-02, 792 A.2d 1208, the court merely listed the § 6 factors and stated that “the initial focus ‘should be on what [policies] the legislature or court intended to protect by having that law apply to wholly domestic concerns, and then, whether these concerns will be furthered by applying that law to the multi-state situation.’ ” Applying that here, the Court notes that the purpose of punitive damages is to punish and deter defendant’s alleged conduct. Mancini v. Township of Teaneck, 349 N.J. Super., 527, 568, 794 A.2d 185 (App. Div. 2002). Because the Court

has found that defendants' conduct alleged to cause injury took place in each plaintiff's home state, those jurisdictions have an interest in governing punitive damages.

### **C. Conclusion**

For the reasons set forth above, the Court concludes that punitive damages are governed by the laws of the individual states.