

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

RUTH DOPSON-TROUTT and
FRANK TROUTT,

Plaintiffs,

v.

Case No.: 8:06-CV-1708-T-24-EAJ

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

ORDER

This cause comes before the Court on Defendant Novartis Pharmaceuticals Corporation's ("NPC") Motion to Apply New Jersey Law to Plaintiffs' Punitive Damages Demand and to Preclude Punitive Damages. [Doc. 114]. Plaintiffs Ruth Dopson-Troutt and Frank Troutt oppose. [Doc. 119]. For the reasons stated herein, Defendant's motion is granted.

I. BACKGROUND

While Ms. Dopson-Troutt was residing in Pennsylvania, she was diagnosed with breast cancer, which later metastasized to her hip and pelvic bones. Her oncologist prescribed Aredia and Zometa, which are bisphosphonate drugs that are produced, sold, and marketed by NPC. Both Aredia and Zometa have been approved by the Food and Drug Administration ("FDA") for the treatment of bone metastasis. From 1999 to 2005, Ms. Dopson-Troutt was infused with Aredia and Zometa. In 2004, Ms. Dopson-Troutt's tooth was extracted.

In 2005, Ms. Dopson-Troutt moved to Florida. In August 2005, she began seeing another oncologist and reported having jaw pain that began after her tooth extraction. Her oncologist

diagnosed her with osteonecrosis of the jaw, caused by her use of Aredia and Zometa and the tooth extraction.

In 2006, Ms. Dopson-Troutt and her husband brought this diversity action against NPC, a Delaware corporation with its principal place of business in New Jersey. Plaintiffs allege that NPC's manufacturing, labeling, marketing, selling, advertising, and distributing of Aredia and Zometa caused their injuries and assert the following claims: (1) strict liability, (2) negligent manufacture, (3) negligent failure to warn, (4) breach of express warranty, (5) breach of implied warranty, and (6) loss of consortium. [Doc. 1]. Plaintiffs seek compensatory damages and punitive damages for all claims. [*Id.* at ¶¶ 23, 29, 37, 41, 45, 46].

This action was transferred to a Multidistrict Litigation Court in the Middle District of Tennessee for consolidated pretrial proceedings with other similar actions brought against NPC, and in 2012, was remanded back to this Court.

In the instant motion, NPC asks the Court to apply New Jersey law to Plaintiffs' punitive damages demands and to preclude punitive damages. [Doc. 114]. NPC argues that: (1) even if Pennsylvania law applies to the other issues in this case, the Court should conduct a separate choice-of-law analysis for the issue of punitive damages; (2) under Florida choice-of-law rules, New Jersey law governs the issue of punitive damages; and (3) Plaintiffs are precluded from seeking punitive damages under New Jersey law.

Plaintiffs argue that: (1) in its summary judgment order this Court found Pennsylvania law controlled and therefore cannot apply a different law to punitive damages; (2) even if a different law could apply to punitive damages, Pennsylvania law would still govern; and (3) even if New Jersey law governs, punitive damages are not precluded.

II. CHOICE OF LAW FOR PUNITIVE DAMAGES

A. Standard

A federal court sitting in diversity must apply the conflict rules of the forum state. *See Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487 (1941). Thus, Florida's choice-of-law rules apply in this case. *See Shapiro v. Associated Int'l Ins. Co.*, 899 F.2d 1116, 1118 (11th Cir. 1990).

To determine which state's substantive law applies to issues arising from tort claims, Florida's choice-of-law rules adopt the "significant relationship" approach set forth in the Restatement (Second) of Conflict of Laws. *See Bishop v. Fla. Specialty Paint, Co.*, 389 So. 2d 999, 1001 (Fla. 1980). This approach requires evaluating the Section 145 factors and Section 6 principles to determine the state with "the most significant relationship to the occurrence and the parties." *Restatement (Second) of Conflict of Laws* § 145 (1971).

Courts evaluate the following contacts set forth in Section 145: (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. *Id.* Courts also must consider the following Section 6 principles: (1) the needs of the interstate and international systems; (2) the relevant policies of the forum; (3) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue; (4) the protection of justified expectations; (5) the basic policies underlying the particular field of law; (6) certainty, predictability and uniformity of result; and (7) ease in the determination and application of the law to be applied. *Id. at* § 6.

B. Dépeçage

Before assessing which state’s law applies to punitive damages in this case, the Court first addresses whether the issue of punitive damages can be governed by a different state’s law under the “dépeçage” doctrine—“a choice of law principle requiring that conflicts be evaluated with respect to a particular issue in a case, rather than to the case as a whole.” *Guenther v. Novartis Pharm. Corp.*, 2013 WL 1225391, at *2 n.1 (M.D. Fla. Mar. 27, 2013).

Dépeçage is a choice-of-law doctrine. *See Foster v. U.S.*, 768 F.2d 1278, 1281 (11th Cir. 1985) (dépeçage is a conflicts of law doctrine); *see also Schippers v. U.S.*, 715 F.3d 879, 888 (11th Cir. 2013) (determining whether Texas permitted dépeçage in diversity case where Texas choice-of-law applied). Therefore, even though the Court found Pennsylvania law governed in its summary judgment order, Florida’s choice-of-law principles, not Pennsylvania’s, apply here.

Plaintiffs also argue that Florida does not recognize dépeçage. [Doc. 119 at 2]. However as explained by Judge Presnell, “Although the word ‘dépeçage’ is a ‘stranger to Florida law,’ the concept it represents is not.” *Guenther*, 2013 WL 1225391, at *2. Courts are not required to evaluate significant relationships “to determine which state’s law should be applied to all issues in the case as a whole; rather the contacts must be evaluated with respect to the particular issue under consideration.” *Id.* (quoting *Stallworth v. Hospitality Rentals, Inc.*, 515 So. 2d 413, 415 (Fla. 1st DCA 1987); *see also Judge v. Am. Motors Corp.*, 908 F.2d 1565, 1578 (11th Cir. 1990) (“Florida courts apply the ‘most significant relationship’ test, not to a collective sum of issues in dispute, but to each individual issue which arises in the case.”). Thus, “different substantive issues in a single case may have to be resolved under the laws of different states where the choices influencing decisions differ.” *Foster*, 768 F.2d at 1281.

This Court agrees with the reasoning of Judge Presnell in *Guenther* and finds that Florida law permits separately examining the Restatement factors with respect to the punitive damages issue in this case. 2013 WL 1225391, at *2; *see also Judge*, 908 F.2d at 1571 n.6 (“the question of which state retains the greatest interest in applying its punitive damage rule should be analyzed separately from the question of which state retains the greatest interest in applying its compensatory damage rule”); *Zimmerman v. Novartis Pharm. Corp.*, 889 F. Supp. 2d 757, 761-62 (D. Md. 2012) (“The ‘significant relationship’ approach allows for ‘dépeçage,’ such that a court can apply different state laws to different issues in a single case—*i.e.*, liability, compensatory damages, and punitive damages.”).

C. Conflict exists between Pennsylvania and New Jersey laws

As another preliminary matter, the Court must determine whether a conflict exists between the states’ laws. Plaintiffs argue that Pennsylvania law governs and NPC argues that New Jersey law governs. Thus, the issue is whether a conflict exists between Pennsylvania law and New Jersey law regarding punitive damages.¹

Under New Jersey law, drug companies are immune from punitive damages in product liability cases where the drug was approved by the FDA, “or is generally recognized as safe and effective pursuant to conditions established by the [FDA] and applicable regulations, including packaging and labeling regulations.” N.J. Stat. Ann. § 2A:58C-5(c). An exception exists if a plaintiff can show that the drug company “knowingly withheld or misrepresented information required to be submitted under the [FDA’s] regulations.”² *Id.* Under Pennsylvania, law, no such immunity exists. “Punitive damages may be awarded for conduct that is outrageous, because of

¹ NPC argues that such a conflict exists. [Doc. 114 at 6-7]. Plaintiffs do not expressly address this issue but imply a conflict exists. [Doc. 119 at 13].

² Even if a plaintiff could make such a showing under New Jersey law, any award would be capped at \$350,000 or five times the compensatory damages award, whichever is greater. *Id.* at § 2A:15-5.14b.

the defendant's evil motive or his reckless indifference to the rights of others.” *Feld v. Merriam*, 485 A.2d 742, 747 (Pa. 1984) (quoting *Restatement of Torts (Second)* § 908(2)).

Thus, a conflict exists between New Jersey and Pennsylvania laws, and under Florida's choice-of-law analysis, the Court must determine whether New Jersey or Pennsylvania has a more significant relationship to the issue of punitive damages.

D. New Jersey has a more significant relationship to punitive damages

The parties do not dispute that Plaintiffs' injuries occurred in Pennsylvania and NPC's principal place of business is located in New Jersey. However, Plaintiffs contend Pennsylvania law should govern punitive damages because Pennsylvania is where the injuries occurred, the conduct causing injury occurred, and the parties' relationship is centered; while NPC contends New Jersey law should govern because it is where the conduct to be punished occurred.

The contacts set forth in Section 145 of the Restatement “are to be evaluated according to their relative importance with respect to the particular issue.” *Restatement (Second) of Conflict of Laws* § 145. Although the “law of the state where the injury occurred” generally applies, *id.* at § 146, “when the primary purpose of the tort rule involved is to deter or punish misconduct, the place where the conduct occurred has peculiar significance.” *Krause v. Novartis Pharm. Corp.*, 2013 WL 785229, at *4 (N.D. Fla. Feb. 28, 2013) (quoting *Restatement (Second) Conflict of Laws* § 145, cmt. e.).

Plaintiffs contend the injury-causing conduct occurred in Pennsylvania, because NPC “plac[ed] the drugs in the stream of commerce and fail[ed] to warn medical treaters in Pennsylvania.” [Doc. 119 at 12]. However, the “alleged misconduct to be punished by a punitive damage award—that is, [NPC]'s decisions as to the labeling, packaging, and warning of

the Aredia and Zometa drugs—occurred in New Jersey,” which is also where NPC’s principal place of business is located. *Krause*, 2013 WL 785229, at *4; *see also Chiles v. Novartis Pharm. Corp.*, 2013 WL 539891, at *2 (M.D. Fla. Feb. 7, 2013) (“the decisions at issue that potentially give rise to punitive damages were made from [NPC]’s New Jersey headquarters”).

The Court agrees with the reasoning of the other courts who have found that the Section 6 Restatement principles support applying New Jersey law to the punitive damages issue in this case. *Krause*, 2013 WL 785229, at *3-4; *Talley v. Novartis Pharm. Corp.*, 2011 WL 2559974, at *4 (W.D.N.C. June 28, 2011); *Zimmerman*, 889 F. Supp. 2d at 764 (adopting the reasoning in *Talley*). New Jersey has made a policy decision to preclude punitive damages in cases involving FDA-approved drugs and “has the greater interest in regulating the conduct of a New Jersey business.” *Krause*, 2013 WL 785229, at *4. Further, “[t]he basic policy underlying punitive damages is to punish and deter [NPC], whose conduct occurred in New Jersey, thus the interests of the tort field are enhanced through consistent application of New Jersey law.” *Talley*, 2011 WL 2559974, at *4.

Accordingly, the Court finds that New Jersey has a more significant relationship to the issue of punitive damages in this case, and New Jersey law should be applied.

III. PRECLUSION OF PUNITIVE DAMAGES

New Jersey Statutes § 2A:58C-5(c) prohibits punitive damages for FDA-approved drugs unless a plaintiff can show that a defendant “knowingly withheld or misrepresented information required to be submitted under the [FDA’s] regulations.” NPC contends Plaintiffs are precluded from seeking punitive damages because that statutory exception requirement is preempted by the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, et. seq., (“FDCA”).

The FDCA requires a drug manufacturer to submit an application and extensive disclosures for the FDA's review when seeking approval of a new drug. *See* 21 U.S.C. § 355(a)-(b). The FDA may deny the application for various reasons, including false or misleading labeling, and may withdraw approval of an application that "contains any untrue statement of a material fact." 21 U.S.C. §§ 355(d), (e). The FDA regulates pharmaceutical drugs and has exclusive authority to initiate enforcement proceedings for violations of the FDCA. *See* 21 U.S.C. § 337(a).

Both parties acknowledge that courts have differed as to whether New Jersey's statutory exception requirement for punitive damages is preempted by the FDCA. As the *Guenther* court explained, *see* 2013 WL 1225391, at *3, this difference of opinion largely turns on a court's conclusion on the applicability of *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the United States Supreme Court found that the plaintiffs' "fraud-on-the-FDA" state claims "exist[ed] solely by virtue of the FDCA disclosure requirement" and "the existence of these federal enactments [was] a critical element in their case." 531 U.S. at 353. The Supreme Court held that these claims were impliedly preempted by the FDCA because they "conflict[ed] with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 351.

This court agrees with those courts that have found that New Jersey's statutory exception requirement is equivalent to a "fraud-on-the-FDA" state claim and thus preempted. As the, *Guenther* and *Zimmerman* courts point out:

Plaintiffs' claim for punitive damages requires a state fact finder to determine what was required to be submitted to the FDA, whether it was submitted to the FDA and, whether the FDA would have made a different approval decision had it been provided with the correct or missing information. Plaintiffs' claim thus requires a fact finder to make these types of determinations as a matter of state

law even though federal law makes such determinations the exclusive province of the FDA.

Guenther, 2013 WL 1225391, at *3 (quoting *Zimmerman*, 889 F. Supp. 2d at 776).

Therefore, Plaintiffs are precluded from seeking punitive damages and their punitive damages claim will be stricken..

IV. CONCLUSION

Accordingly, it is ORDERED that Defendant's Motion to Apply New Jersey Law to Plaintiffs' Punitive Damages Demand and to Preclude Punitive Damages [Dkt. 114] is

GRANTED.

DONE AND ORDERED at Tampa, Florida, this 22nd day of July, 2013.


SUSAN C. BUCKLEW
United States District Judge

Copies to: Counsel of record