IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

ALLEN WILLIAMS, as Executor of the Estate of Barbara Bowles, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORP., Defendant	:	Case No. 3:12-cv-145 JUDGE WALTER H. RICE

SHIRLEY SHEFFER, *et al.*, Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORP., Defendant	:	Case No. 3:12-cv-238 JUDGE WALTER H. RICE

DECISION AND ENTRY SUSTAINING NOVARTIS PHARMACEUTICALS CORPORATION'S MOTION TO FIND THAT PUNITIVE DAMAGES ARE UNAVAILABLE (DOC. #69 IN CASE NO. 3:12-cv-145, and DOC. #66 IN CASE NO. 3:12-cv-238)

This matter is currently before the Court on Defendant Novartis Pharmaceuticals Corporation's Motion to Find that Punitive Damages are Unavailable. (Doc. #69 in Case No. 3:12-cv-145, and Doc. #66 in Case No. 3:12-cv-238). Novartis has filed identical motions in both of the above-captioned products liability cases, which are set for trial later this year.

Plaintiffs allege that Novartis knew or should have known that its bisphosphonate drugs, Aredia® and Zometa®, cause osteonecrosis of the jaw, and failed to adequately warn patients and the medical community of this risk. In addition to compensatory damages, Plaintiffs seek punitive damages, alleging corporate misconduct. Novartis argues that New Jersey law applies and, because the drugs are FDA-approved, and because the FDA has made no finding of fraud or misrepresentation, punitive damages are not available. Plaintiffs argue that Ohio law applies, and that genuine issues of material fact preclude dismissal of the claims for punitive damages. For the reasons set forth below, the Court SUSTAINS Novartis's motions.

The parties agree that, because both of the above-captioned cases were originally filed in the United States District Court for the District of Columbia, the District of Columbia's choice-of-law rules apply. *Ferens v. John Deere Co.*, 494 U.S. 516, 522-23 (1990). The parties also agree that Ohio law governs Plaintiffs' claims with respect to the issues of liability and compensatory damages. "The issue of punitive damages is distinct from that of liability for the underlying claims, however, and choice of law for that issue must be analyzed separately." *Minebea Co., Ltd. v. Papst*, 337 F. Supp. 2d 34, 40 (D.D.C. 2005).

Under the District of Columbia's choice-of-law rules, the court first determines whether there is a conflict among the laws of the states that have an interest in the issue to be adjudicated. A conflict exists if application of the laws would produce a different result. If there is a conflict, the court determines which

law to apply by analyzing the competing "governmental interests" and determining which state has the most significant relationship to the issue. *Estate of Doe v. Islamic Republic of Iran*, 808 F. Supp. 2d 1, 20 (D.D.C. 2011) (quoting *USA Waste of Md., Inc. v. Love*, 954 A.2d 1027, 1032 (D.C. 2008)). In making this determination, courts generally consider four factors: "(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 is centered." *Washkoviak v. Student Loan Marketing Ass'n*, 900 A.2d 168, 180 (D.C. 2006) (citing *Restatement (Second) of Conflict of Laws* § 145(2)(a)-(2)(d)).

The court also considers the "needs of the interstate and the international systems, the relevant policies of the forum, the relevant policies of other interested states, certainty, predictability and uniformity of result, and ease in the determination and application of the law to be applied." *Estate of Doe*, 808 F. Supp. 2d at 21 (citing *Restatement (Second) of Conflict of Laws* § 6(2)). "As a general rule, the law of the forum governs, 'unless the foreign state has a greater interest in the controversy.'" *Id.* (quoting *Kaiser–Georgetown Cmty. Health Plan v. Stutsman*, 491 A.2d 502, 509 (D.C. 1985)).

In this case, Ohio and New Jersey both have an interest in the question of whether punitive damages may be awarded. Ohio has an interest because Plaintiffs reside here and this is where the injuries occurred. New Jersey also has

an interest because Novartis is headquartered there and that is where the alleged corporate misconduct occurred.

The relevant Ohio and New Jersey statutes governing punitive damages in pharmaceutical products liability cases are very similar, but not identical. The Ohio law provides, in relevant part:

> (C)(1) Except as provided in division (C)(2) of this section, if a claimant alleges in a product liability claim that a drug or device caused harm to the claimant, the manufacturer of the drug or device shall not be liable for punitive or exemplary damages in connection with that product liability claim if the drug or device that allegedly caused the harm satisfies either of the following:
>
> > (a) It was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301-392, as amended, or the "Public Health Service Act," 58 Stat. 682 (1944), 42 U.S.C. 201-300cc-15, as amended.
>
> * * *
>
> (2) Division (C)(1) of this section does not apply if the claimant establishes, by a preponderance of the evidence, that the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type.

Ohio Rev. Code § 2307.80.

> The New Jersey statute reads as follows:
>
> Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 *et seq*. or the "Public Health Service

> Act," 58 Stat. 682, 42 U.S.C. § 201 *et seq.* and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. 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-5(c).

On their face, both statutes contain an exception, allowing for punitive damages in cases of "fraud-on-the-FDA." Nevertheless, in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341, 347-38 (2001), the Supreme Court held that a state law "fraud-on-the-FDA" claim implicates "the relationship between a federal agency and the entity it regulates," and is impliedly preempted.

In reliance on *Buckman*, Ohio and New Jersey courts have both held that these statutory exceptions are impliedly preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* In *McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 276 (N.J. Super. Ct. App. Div. 2008), the court found implied preemption because the "punitive damages provisions of N.J.S.A. 2A:58C-5 impinge upon federal statute and regulation." Likewise, in *Decker v. GE Healthcare, Inc. (In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.)*, Nos. 1:08GD50000, 1:12GD50004, 2013 WL 587655 (N.D. Ohio Feb. 13, 2013), the court noted that to allow a court to make an independent finding of fraud "would lead to 'inter-branch-meddling.'" *Id.* at *14 (citing *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004)). *See also Marsh v. Genentech, Inc.*, 693 F.3d

546, 550-51 (6th Cir. 2012) (holding that similar exception under Michigan statute was impliedly preempted).[1] Therefore, the "fraud-on-the-FDA" exception is not available under either Ohio law or New Jersey law.

It is undisputed that the drugs in question were approved by the FDA. Whereas New Jersey law broadly prohibits an award of punitive damages if the drug is FDA-approved, Ohio grants immunity from punitive damages only if the drug was also "manufactured and labeled in relevant and material respects" in accordance with the terms of the FDA approval.

Citing *Burdine v. Stryker Corporation*, 766 F. Supp. 2d 837, 838-39 (N.D. Ohio 2011), Plaintiffs argue that it is premature for the Court to decide whether

---

[1] Plaintiffs note that juries in New York and Florida, in two other cases involving Aredia® and Zometa®, found that Novartis withheld material information from the FDA. Punitive damages were awarded in one of those cases. *See Davids v. Novartis Pharms. Corp.*, No. CV06-0431 (E.D.N.Y. Nov. 2, 2012), and *Chiles v. Novartis Pharms. Corp.*, No. 3:06-cv-0096 (M.D. Fla. March 27, 2013), Docs. ##72-1 and 72-2. Plaintiffs maintain that, as a result of these jury verdicts, Novartis is now collaterally estopped from arguing that it did not withhold material information from the FDA.

However, the Sixth Circuit has held that "fraud-on-the-FDA" claims are viable only if the *FDA itself* makes a finding that the drug manufacturer engaged in fraud or misrepresentation. *See In re Aredia & Zometa Prods. Liab. Litig.*, 352 F. App'x 994, 994 (6th Cir. 2009) (holding that the FDCA preempts fraud-on-the-FDA claims "unless some federal agency has already found the requisite fraud on the FDA."); *Decker*, 2013 WL 587655, at *14 ("a punitive damages claim for an FDA-approved drug is allowed under Ohio law *only if* the FDA has made a finding or either fraud or misrepresentation"). It is undisputed that the FDA has made no such finding in these cases.

Plaintiffs also argue that application of the doctrine of implied preemption achieves a result contrary to the intent of the state legislatures. This may well be true. However, the question of whether a drug manufacturer has engaged in fraud or misrepresentation is a matter committed exclusively to the FDA. *See Zimmerman v. Novartis Pharms. Corp.*, 889 F. Supp.2d 757, 764-778 (D. Md. 2012) (engaging in a thorough analysis of the doctrine of implied preemption).

the punitive damages claim should be dismissed, since there are genuine issues of material fact concerning whether Novartis complied with the relevant FDA manufacturing and labeling requirements.

In support of this argument, Plaintiffs state only that "[t]he testimony of Dr. [Suzanne] Parisian on this point raises a material question of fact." Doc. #72, PageID#8689. Unfortunately, Plaintiffs fail to cite to any particular portion of Dr. Parisian's testimony. The Court is not obligated to dig through the record to determine whether there is a genuine issue of material fact therein.

A cursory review of the record suggests that Plaintiffs do not allege that Novartis failed to manufacture the drugs in accordance with the terms of the FDA approval, or that the labels on the drugs varied in any material way from the labels approved by the FDA. Rather, Plaintiffs' allegations appear to focus instead on Novartis's conduct prior to obtaining FDA approval, and on its failure to comply with post-marketing requirements. Such allegations are akin to claims of "fraud-on-the-FDA," and would be impliedly preempted. *See Marsh v. Genentech, Inc.*, 693 F.3d 546, 552-53 (6th Cir. 2012) (interpreting a similar Michigan statute).

Nevertheless, for purposes of the conflict-of-laws analysis, the Court will assume *arguendo* that there is a genuine issue of material fact concerning whether the drugs were manufactured and labeled in accordance with the terms of the FDA approval. If Novartis is unable to satisfy its burden of proof on this issue at trial, then punitive damages would be available under Ohio law. In contrast, under New

Jersey law, because the drugs were FDA-approved, and because the fraud-on-the-FDA exception is impliedly preempted, punitive damages are not available.

Because there is a conflict between Ohio law and New Jersey law on punitive damages, the Court must analyze the competing "governmental interests" of both states to determine which state has the most significant relationship to the issue. *Estate of Doe*, 808 F. Supp. 2d at 20. As previously noted, the District of Columbia has adopted the *Restatement (Second) of Conflict of Laws*, § 145, which requires consideration of "(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 is centered." *Washkoviak*, 900 A.2d at 180.

In *Keene Corp. v. Insurance Co. of North America*, 597 F. Supp. 934, 938-39 (D.D.C. 1984), the United States District Court for the District of Columbia explained:

> When the primary purpose of a rule of law is to deter or punish conduct, the States with the most significant interests are those in which the conduct occurred and in which the principal place of business and place of incorporation of defendant are located. *See Restatement (Second) of Conflict of Laws* § 145 comments c-e; *In Re Air Crash Disaster Near Chicago, Illinois*, 644 F.2d at 613. The State of domicile of plaintiff has no interest in imposing punitive damages. "The legitimate interests of [plaintiffs' domiciliary] states, after all, are limited to assuring that the plaintiffs are adequately compensated for their injuries. . . . Once the plaintiffs are made whole by recovery of the full measure of compensatory damages to which they are entitled under the law of their domiciles, the interests of those States are satisfied." *In Re Air Crash Disaster Near Chicago, Illinois*, 644 F.2d at 613. The place where the injury occurred and where the parties'

> relationship is centered do not claim as great an interest in the punitive damages issue as in other tort-related issues.

Keene Corp. v. Ins. Co. of N. Am., 597 F. Supp. 934, 938-39 (D.D.C. 1984). *See also Minebea*, 377 F. Supp. 2d at 40-41.

Accordingly, although Bowles and Sheffer were domiciled in Ohio and their injuries occurred in Ohio, the Court must give greater weight to "the place where the conduct causing the injury occurred." In this case, the alleged corporate misconduct giving rise to the claims for punitive damages occurred in New Jersey, where Novartis has its principal place of business. It is there that Novartis allegedly failed to conduct adequate clinical trials, failed to disclose material information to the FDA, and made decisions about the warnings that would be placed on the drug labels.

The vast majority of courts that have addressed this issue in other cases involving Aredia® and Zometa® have concluded that New Jersey has the most significant relationship to the punitive damage claims. *See, e.g., Krause v. Novartis Pharms. Corp.*, 926 F. Supp. 2d 1306 (N.D. Fla. 2013) (collecting cases); *Mathews v. Novartis Pharms. Co.*, 953 F. Supp. 2d 811, 815-16 (S.D. Ohio 2013 (collecting cases); *Guenther v. Novartis Pharms. Corp.*, No. 6:08-cv-456, 2013 WL 1225391, at *2 (M.D. Fla. March 27, 2013) (collecting cases).

There is at least one case, however, that holds to the contrary. Plaintiffs cite to *Rowland v. Novartis Pharmaceuticals Corp.*, -- F. Supp. 2d --, 2013 WL 6145119 (W.D. Pa. Nov. 22, 2013), in which the court, applying the District of

Columbia's choice-of-law rules, found that Pennsylvania, where the plaintiff resided, had a greater interest than New Jersey did in the issue of punitive damages. The court stated that "[i]n prescription drug products liability cases involving an alleged failure to warn, the conduct causing the injury occurs primarily where the injured party was prescribed and ingested the drug." *Id.* at *7 (citing *Bortell v. Eli Lilly and Co.*, 406 F. Supp. 2d 1, 5 (D.D.C. 2005)).

Given that the drug was marketed, sold, and administered in Pennsylvania, the *Rowland* court concluded that the "conduct causing the injury" occurred there. In balancing the policy interests of the two states, the court acknowledged that New Jersey had an interest in insulating its corporate citizens from punitive damages, but found that Pennsylvania had a greater interest in regulating conduct that occurs within its borders. *Id.* at **8-9. The *Rowland* court conceded that this decision was contrary to that of most other courts adjudicating Aredia® and Zometa® cases, but found the reasoning of the other cases unpersuasive. *Id.* at *11. It instead relied on *Long v. Sears Roebuck & Co.*, 877 F. Supp. 8 (D.D.C. 1995), *Lakie v. SmithKline Beecham*, 965 F. Supp. 49 (D.D.C. 1997), and various district court cases from Pennsylvania.

In the Court's view, *Rowland* was wrongly decided, and its reliance on *Bortell*, *Lakie*, and *Long* is misplaced. *Bortell* was a products liability case involving diethylstilbestrol or "DES," a drug that often caused infertility and other problems in children whose mothers had taken the drug while pregnant. Contrary to the proposition for which the *Rowland* court cited it, there is no indication that

plaintiff's claims in *Bortell* were based on a "failure-to-warn" theory. Nor is there any indication that plaintiff sought punitive damages. With respect to the issue of liability, the court had to decide whether to apply the law of California, where the plaintiff resided, or the law of Pennsylvania, where the plaintiff's mother was prescribed the drug, and where the plaintiff was exposed to the drug *in utero.* Not surprisingly, the court concluded that "most of the conduct causing plaintiff's injuries occurred in Pennsylvania," and Pennsylvania had the most significant relationship to the claim. *Bortell*, 406 F. Supp. 2d at 5.

In *Lakie*, a Virginia resident brought a products liability action in the United States District Court for the District of Columbia against a dental adhesive manufacturer. Applying the District of Columbia's choice-of-law rules, the court determined that Virginia law applied to the claims of strict liability, fraud and misrepresentation, breach of warranty, and punitive damages. In so holding, the court noted that the manufacturer's only connection to the District of Columbia was that it conducted business there, as it did elsewhere. It also noted that the District of Columbia had no interest in applying its own law since "neither party is a resident and no tortious conduct occurred here." *Lakie*, 965 F. Supp. at 58-59. *Lakie* is clearly factually distinguishable on this basis.

In *Long*, a Maryland resident, who was injured when his riding lawn mower rolled over, filed suit in the District of Columbia. He sued the seller and the manufacturer, alleging negligence, strict liability, and breach of warranty based on representations made by the salesperson in the District of Columbia, where he had

purchased the mower. The court found that District of Columbia law applied to the substantive claims. The court devoted just one paragraph to the question of whether Maryland law or District of Columbia law would apply to the claim for punitive damages, summarily concluding that the District of Columbia had the more significant relationship because "[i]f punitive damages are awarded, they would serve to punish the defendants for conduct occurring in the District of Columbia and would deter similar conduct from occurring in the District of Columbia." *Long*, 877 F. Supp. at 13.

Notably, none of the parties in *Long* argued that the law of New York, where the seller was incorporated, or South Carolina, where the tractor was designed and manufactured, should be applied to the punitive damages issue. Rather, the court was asked to choose between applying the law of the state where the injury occurred (Maryland), or the place where the alleged misrepresentations were made (District of Columbia). It is significant that, given this choice, the court applied the law of the state where defendant engaged in the alleged misconduct.

In the Court's view, under the circumstances presented here, the *Rowland* court erred in finding that Pennsylvania was "the place where the conduct causing the injury occurred." When a plaintiff seeks punitive damages against a manufacturer in a products liability case based on a "failure to warn" theory, the focus, for purposes of a choice-of-law analysis, needs to be on the place where the defendant's alleged corporate misconduct occurred. *See Restatement (Second) Conflict of Laws* § 145 cmt. e ("when the place of the injury . . . is fortuitous . . .

the place where the defendant's conduct occurred will usually be given particular weight . . . "). In this case, the vast majority of the alleged corporate misconduct took place at Novartis's headquarters in New Jersey. That is "the place where the conduct causing the injury occurred."

In determining which state has the most significant relationship to the punitive damages issue, the Court must also consider the policy considerations set forth in *Restatement (Second) of Conflict of Laws* § 6.[2] These factors also support the application of New Jersey law. *See Zimmerman v. Novartis Pharms. Corp.*, 889 F. Supp. 2d 757, 763-64 (D. Md. 2012). Ohio's interest in making sure that its residents are adequately compensated for injuries occurring within its borders is satisfied by the application of Ohio law to the issue of liability.

Admittedly, Ohio may also have some interest in punishing and deterring manufacturers who market dangerous drugs to its citizens. However, when the corporate conduct at issue occurs outside Ohio, that interest is generally outweighed by the interest of the state where the alleged misconduct occurred. As the court held in *Brown v. Novartis Pharmaceuticals Corp.*, No. 7:08-cv-130, 2012 WL 3066588, at * 8 (E.D.N.C. July 27, 2012), Novartis has a justified expectation that New Jersey law will govern the question of whether punitive

---

[2] These include: (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) of Conflict of Laws* § 6.

damages are warranted for its conduct within that state, and "application of New Jersey law to the issue of punitive damages will promote certainty, predictability, and uniformity of result."

For these reasons, the Court joins the vast majority of other courts in holding that New Jersey law governs the question of punitive damages. Because Aredia® and Zometa® are FDA-approved drugs, and because New Jersey's statutory exception for a claim based on "fraud-on-the-FDA" is impliedly preempted, Plaintiffs cannot recover punitive damages. Accordingly, the Court SUSTAINS Defendant Novartis's Motion to Find that Punitive Damages are Unavailable in both of the above-captioned cases. (Doc. #69 in Case No. 3:12-cv-145, and Doc. #66 in Case No. 3:12-cv-238).

Date: April 21, 2014

WALTER H. RICE
UNITED STATES DISTRICT JUDGE