IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

NO. 7:08-CV-130-FL

VICTOR BROWN, and MARTHA BROWN, Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	)	ORDER (Redacted)

This matter is before the court on various pre-trial motions.[1] The court first addresses several pending motions to seal (DE ## 132, 146, and 156).[2] In addition, the court takes up defendant's motion to apply New Jersey law to the issue of punitive damages (DE # 46), defendant's motion *in limine* to exclude evidence concerning adverse drug experience reports (DE # 103), defendant's motion *in limine* to exclude evidence based on incorrect legal standards (DE # 114), certain remaining portions of defendant's omnibus motion *in limine* (DE # 116), and defendant's motion *in limine* to exclude evidence of its subsequent knowledge or conduct (DE # 121). These motions received supplemental briefing pursuant to the court's directive at motions hearing held February

[1] The court does not take up here defendant's motion *in limine* to exclude evidence or argument that defendant should have warned about certain risks earlier than it did (DE # 113), defendant's motion *in limine* to exclude certain inadmissible statements in plaintiff Victor Brown's medical records (DE # 119), defendant's motion *in limine* to exclude certain testimony by Dr. Yoh Sawatari (DE # 123), or those portions of defendant's motion to exclude testimony of plaintiffs' expert Dr. Suzanne Parisian (DE # 51) not previously disposed of at motions hearing held February 3, 2012. These motions remain pending for future disposition.

[2] The parties in these three motions move to seal filings and/or exhibits that relate to the motions *in limine* decided herein. The court does not take up here other pending motions to seal, namely those lodged in the docket at entry numbers 101, 182, and certain portions of 132. Where these latter motions to seal pertain to motions *in limine* not adjudicated here, the court holds them in abeyance for future ruling.

3, 2012. Accordingly, these motions are ripe for adjudication, and the court orders as follows.

BACKGROUND

This case was originally filed in 2005 and arises out of plaintiff Victor Brown's experience with two drugs, Aredia and Zometa, manufactured by Novartis Pharmaceuticals Corporation ("defendant"). Mr. Brown, a multiple myeloma survivor, asserts that his use of Aredia and Zometa caused him to develop osteonecrosis of the jaw ("ONJ"). He seeks compensatory and punitive damages, and his wife, Martha Brown, seeks damages for loss of consortium.

Plaintiffs' case against defendant was consolidated with similar cases pursuant to the Multidistrict Litigation Act, 28 U.S.C. § 1407, and assigned to United States District Judge Todd J. Campbell in the Middle District of Tennessee ("the MDL court"). In order on summary judgment entered December 7, 2010, the MDL court dismissed plaintiffs' claims for strict liability, design defect, manufacturing defect, and negligence *per se*. Plaintiffs' claims for negligent failure to warn and loss of consortium remain. The case was remanded to this court on December 17, 2010.

On June 3, 2011, defendant filed motion to apply New Jersey law to the issue of punitive damages (DE # 46), which motion the court takes up below. Defendant then filed Daubert motions to exclude the testimony of plaintiffs' experts Dr. Suzanne Parisian (DE # 51) and Dr. Robert Marx, D.D.S. (DE # 59). Plaintiffs responded to the three motions, defendant replied, and they were submitted to the magistrate judge for memorandum and recommendation ("M&R"). Finally, on December 2, 2011, defendant filed eleven motions *in limine*, and plaintiff filed one.

The court held motions hearing in New Bern on February 3, 2012. In addition to discussing pre-trial procedures with the parties, the court heard argument on and adjudicated several of the motions *in limine*. Where the court could not reach a decision on several motions based on the

inadequacy of material before it, supplemental briefing was directed, as memorialized in order entered March 5, 2012. At hearing, the court adopted as its own the determination of the magistrate judge concerning the testimony of Dr. Marx, where no party objected to the M&R.

As directed, the parties filed supplemental briefing on May 1, 2012, and responded to same on May 25, 2012. By order entered July 12, 2012, the court scheduled jury selection for September 14, 2012, at 9:30 a.m. in New Bern,[3] with trial to commence September 17, 2012. The court also set a final pretrial conference for 9:30 a.m. on September 7, 2012.

DISCUSSION

A. Motions to Seal (DE ## 132, 146, 156)

1. Defendant's Motion to Seal (DE # 132)

The parties have filed several motions to seal, three of which relate to motions addressed in subsequent sections below. First, on December 2, 2011, defendant filed motion to seal documents lodged in the docket at entry numbers 125 through 131 (DE # 132). Docket entry number 125, an e-mail from Ye Hua to Alan Jenkins, dated March 9, 2005, attaches as Exhibit 7 to defendant's memorandum in support of its omnibus motion *in limine* (DE # 117). In addition, docket entry number 127, an e-mail from Dionigi Maladorno to Katalin Renner, dated April 30, 2003, attaches as Exhibit 4 to defendant's memorandum in support of its motion *in limine* to exclude evidence based on incorrect legal standards (DE # 115). Where docket entry numbers 126 and 128 through 131 do not relate to motions decided herein, the court holds in abeyance the motion to seal as to these documents for future ruling.

Before granting a motion to seal, courts must first give the public notice and a reasonable

[3] The time of jury selection on this date recently was changed to 1:30 p.m.

opportunity to challenge the motion, and courts must then examine the public's right to access in conformity with Stone v. Univ. of Md. Med. Sys. Corp., 855 F.2d 178, 181 (4th Cir. 1988). The common law presumes a right to inspect and copy judicial records and documents. Id. at 180. The presumption may be overcome if competing interests outweigh the interest in access. Id. If the court finds that the public's right to access is outweighed by another significant interest, then the court must consider whether there are less drastic alternatives to sealing. Id. at 181.

No objection has been raised as to defendant's motion to seal docket entries 125 and 127, which motion was filed December 2, 2011. These entries contain confidential and proprietary information which could be harmful to defendant if revealed to the marketplace. The risk of harm outweighs any public right to access, and the alternatives to sealing are inadequate. Accordingly, for the reasons set forth in defendant's memorandum in support of its motion to seal, the court finds good cause to GRANT IN PART defendant's motion (DE # 132). The clerk of court is DIRECTED to seal docket entry numbers 125 and 127.

2. Plaintiffs' Motion to Seal Response to Defendant's Omnibus Motion *in Limine* (DE # 146)

On December 16, 2011, plaintiffs filed motion for leave to file under seal their response to defendant's omnibus motion *in limine* (DE # 146), where said response referenced and attached as exhibits deposition transcript excerpts designated confidential by defendant. However, in response dated December 29, 2011, defendant informs that it does not request that plaintiffs' opposition or exhibits thereto be sealed. Accordingly, plaintiffs' motion to seal (DE # 146) is DENIED AS MOOT. The clerk of court is DIRECTED to unseal the document provisionally filed under seal at entry number 145 and all attachments thereto.

3. Plaintiffs' Motion to Seal Objections to the Magistrate Judge's M&R (DE # 156)

Plaintiffs move to seal their objections to the magistrate judge's December 16, 2011 M&R, as well as Exhibits 5 and 6 attached thereto. Plaintiffs inform that the exhibits are excerpts from deposition transcripts of David R. Epstein and Rainer Boehm, designated as confidential by defendant pursuant to the terms and provisions of the Confidentiality Order entered by the MDL court. Further, plaintiffs' objection quotes at length from the deposition transcripts in question.

Defendant, in response, urges that plaintiffs' objections and the relevant exhibits be sealed. Defendant maintains that the deposition testimony was properly designated as confidential under the MDL protective order. Further, defendant states that Dr. Epstein and Dr. Boehm gave testimony regarding the organization and business decision-making process of defendant's ultimate parent corporation, which is in Switzerland and is not a defendant in the case.

The court finds that Exhibits 5 and 6 contain confidential and proprietary information which could be harmful to defendant if revealed to the marketplace. The risk of harm outweighs any public right to access, and the alternatives to sealing are inadequate. Accordingly, for the reasons set forth more particularly in defendant's response to plaintiffs' motion to seal, the court finds good cause to GRANT IN PART plaintiffs' motion to seal (DE # 156). The clerk of court is DIRECTED to maintain as sealed docket entries 155-5 and 155-6. The clerk is further DIRECTED to unseal those filings provisionally sealed at docket entries 155-1 through 155-4. Finally, the court GRANTS IN PART plaintiffs' request to seal their objections to the M&R. While the court upon its review finds that pages 8 through 10 of plaintiffs' objections discuss particularly the noted deposition excerpts, the court does not find cause to seal the entire document. Where the CM/ECF system does not have the capability to maintain specific pages of documents under seal, the clerk of court is DIRECTED

to maintain plaintiffs' objections (DE # 155) under seal. However, plaintiffs shall file within fourteen (14) days of entry of this order a redacted version of their objections, redacting only those portions pertaining to the relevant deposition excerpts.

B. Defendant's Motion to Apply New Jersey Law to the Issue of Punitive Damages (DE # 46)

1. Standard of Review

The court takes up defendant's motion to apply New Jersey law to the issue of punitive damages (DE # 46) with benefit of Magistrate Judge Daniel's memorandum and recommendation ("M&R"), lodged in the docket at entry number 144. This court reviews *de novo* those portions of a magistrate judge's M&R to which specific objections are filed. 28 U.S.C. § 636(b). The court does not perform a *de novo* review where a party makes only "general and conclusory objections that do not direct the court to a specific error in the magistrate's proposed findings and recommendations." Opriano v. Johnson, 687 F.2d 44, 47 (4th Cir. 1982). Absent a specific and timely filed objection, the court reviews only for "clear error" and need not give any explanation for adopting the M&R. Diamond v. Colonial Life & Acc. Ins. Co., 416 F.3d 310, 315 (4th Cir. 2005); Camby v. Davis, 718 F.2d 198, 200 (4th Cir. 1983). Upon careful review of the record, "the court may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge." 28 U.S.C. § 636(b)(1).

2. Analysis

The parties agree that the court must look to Tennessee choice-of-law jurisprudence to determine the law applicable to the issue of punitive damages, where plaintiffs originally filed suit in the United States District Court for the Middle District of Tennessee, and the case was transferred to this court pursuant to 28 U.S.C. § 1404(a). Def.'s Mem. 2; Pls.' Resp. 3; see also Ferens v. John

Deere Co., 494 U.S. 516, 519 (1990) (following a transfer under 28 U.S.C. § 1404(a) initiated by defendant or plaintiff, the transferee court must follow the choice-of-law rules of the transferor court).

a. Conflict of Law

Plaintiffs ask the court to apply North Carolina law to the issue of punitive damages. Defendant requests application of New Jersey law. Under Tennessee choice-of-law rules, the court must first determine whether there is a conflict between North Carolina and New Jersey law as to punitive damages. Hataway v. McKinley, 830 S.W.2d 53, 55 (Tenn. 1992). Each state allows generally for punitive damages if plaintiff proves by clear and convincing evidence certain aggravating factors in addition to entitlement to compensatory damages. See N.C. Gen. Stat. § 1D-15(a)-(b), N.J. Stat. Ann. § 2A:15-5.12(a). Similarly, each state caps punitive damages at a certain amount. North Carolina law provides that punitive damages shall not exceed three times the compensatory damages award, or $250,000, whichever is greater. Id. § 1D-25(a)-(b). New Jersey caps punitive damages at the greater of five times compensatory damages or $350,000. Id. § 2A:15-5.14(b).

Despite the similarities, however, New Jersey places a key limitation on punitive damages not present in North Carolina. Under New Jersey law, "[p]unitive damages shall not be awarded if a drug . . . which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration . . . and was approved or licensed," unless "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." N.J. Stat. Ann. § 2A:58C-5(c). Further, in McDarby v. Merck & Co., Inc., a New Jersey intermediate

appellate court held that the exception in § 2A:58C-5(c) permitting punitive damages if the manufacturer "knowingly withheld or misrepresented information" from the FDA was preempted by the Federal Food Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.* McDarby v. Merck & Co., 401 N.J. Super. 10, 99, 949 A.2d 223, 279 (App. Div. 2008) See also Forman v. Novartis Pharmaceuticals Corp., 793 F. Supp. 2d 598, 601 (E.D.N.Y. 2011). Accordingly, as the parties acknowledge, New Jersey's law as to punitive damages in a pharmaceutical products liability case such as this one differs from North Carolina's. The court must therefore further apply Tennessee's choice-of-law analysis to determine which state's punitive damages law applies.

b. Tennessee's Choice-Of-Law Analysis

In resolving conflicts of law questions in tort cases, Tennessee applies the "most significant relationship" approach of the Restatement (Second) of Conflict of Laws (1971). Hataway, 830 S.W.2d at 59. Thus, the rights and liabilities of the parties here as to punitive damages "are determined by the local law of the state which, with respect to [punitive damages], has the most significant relationship to the occurrence and the parties under the principles stated in § 6 [of the Restatement (Second)]." Restatement (Second) of Conflict of Laws § 145(1). Contacts to be considered in applying the principles of § 6 include: "(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. § 145(2). Pursuant to § 6, the factors relevant to the choice of the applicable rule of law 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, unpredictability and uniformity of result, and
(g) ease in the determination and application of the law to be applied.

Id. § 6(2).

Here, the parties agree that North Carolina law applies to issues of liability and compensatory damages, because plaintiffs reside in North Carolina and all relevant medical and dental treatment occurred there. Def.'s Mem. 2; Pls.' Resp. 2. Defendant argues, however, that New Jersey law should apply to the issue of punitive damages. "Because the conduct that plaintiffs contend warrants the imposition of punitive damages occurred at the corporate level, the law of the jurisdiction in which the corporation is headquartered, here New Jersey, should govern the imposition of punitive damages." Def.'s Mem. 4. Plaintiffs respond that North Carolina law, in addition to governing questions of liability and compensatory damages, should also govern punitive damages, because Mr. Brown lived in North Carolina and obtained all medical care there.

c. Tennessee's Choice-of-Law Jurisprudence Permits Dépeçage.

First, the court must determine whether Tennessee choice-of-law jurisprudence permits dépeçage, a principle allowing for application of the laws of different jurisdictions to different issues – for example, the application of one state's law as to compensatory damages and another's as to punitive. Plaintiffs, in objection to M&R, contend that Tennessee choice-of-law jurisprudence does not permit dépeçage, although they cite no authority for this proposition. In Hataway, the Supreme Court of Tennessee, after considering in detail several conflicts theories, expressly adopted the approach of the Restatement (Second) for application to tort cases. The Restatement (Second) repeatedly states that the law of the state with the most significant relationship to a specific issue

shall be applied. See Restatement (Second) of Conflict of Laws §§ 145, 146. Further, commentary to the Restatement provides for dépeçage. See id. § 145 cmt. d ("The courts have long recognized that they are not bound to decide all issues under the local law of a single state . . . Each issue is to receive separate consideration if it is one which would be resolved differently under the local law rule of two or more of the potentially interested states"). Indeed, a Reporter's Note to Restatement (Second) § 171, which section governs choice of law as to damages, provides,

> The law governing the right to exemplary damages need not necessarily be the same as the law governing the measure of compensatory damages. This is because situations may arise where one state has the dominant interest with respect to the issue of compensatory damages and another state has the dominant interest with respect to the issue of exemplary damages.

Id. § 171, Reporter's Note, cmt. d. Based on the foregoing, the court finds that Tennessee choice-of-law jurisprudence allows for dépeçage. See also Talley v. Novartis Pharmaceuticals Corp., 3:08-CV-361-GCM, 2011 WL 2559974, at *2 (W.D.N.C. June 28, 2011) reconsideration denied, 3:08-CV-00361, 2011 WL 3515858 (W.D.N.C. Aug. 11, 2011).

d. Contacts Set Forth in Restatement (Second) § 145(2)

The court next considers those contacts set forth in Restatement (Second) § 145(2), with instruction that they "are to be evaluated according to their relative importance with respect to the particular issue." Restatement (Second) of Conflict of Laws § 145(2). Here, plaintiffs allege that injury occurred in North Carolina. Further, North Carolina is the domicile of plaintiffs and the place where the parties' relationship is centered, as Mr. Brown was treated and prescribed the relevant medication in North Carolina. Defendant is incorporated in Delaware and has principle offices in New Jersey. Ans. ¶ 2. However, more weight should be placed on defendant's contact with New Jersey than Delaware, where "a corporation's principal place of business is a more important contact

than the place of incorporation." Restatement (Second) of Conflict of Laws § 145, cmt. e; see also Kelly v. Ford Motor Co., 933 F. Supp. 465, 469 (E.D. Pa. 2006).

The most contested contact, set forth in § 145(2), is "the place where the conduct causing the injury occurred." Plaintiffs emphasize that defendant marketed, sold, and distributed Aredia and Zometa in North Carolina, where Mr. Brown purchased them. Defendant replies, however, that its "communications regarding Aredia and Zometa originated from New Jersey, based on marketing materials developed in New Jersey and drug labeling approved by the FDA based on data provided by [defendant] from New Jersey." Def.'s Repl. 7.

The court does not find convincing plaintiffs' argument that all relevant decisions would have been made in Basel, Switzerland, which plaintiffs assert is the primary location for Novartis. To begin, plaintiffs' second amended complaint identifies defendant as having its principal place of business in East Hanover, New Jersey, and it makes no reference to Switzerland. Further, the FDA approval letter for Zometa is addressed to defendant in East Hanover, New Jersey. See Def.'s Mot., Ex. 4. [redacted] Nor have other courts been compelled by plaintiffs' argument that all relevant decisions occurred in Switzerland, particularly where plaintiffs do not request for Swiss law to be applied. See Talley, 2011 WL 2559974, at *3; see also Deutsch v. Novartis Pharmaceuticals Corp., 723 F. Supp. 2d 521, 525 (E.D.N.Y. 2010) ("However, the Plaintiffs have not urged the Court to apply Swiss law, and for an obvious reason: punitive damages are not permitted under Swiss law") (citing Exxon Shipping Co. v. Baker, 554 U.S. 471, 497 (2008) (noting that Swiss law does not permit punitive damages)).

Based on the foregoing, this court joins others that have confronted the issue in finding that defendant's conduct relevant to the determination of punitive damages occurred in New Jersey. See Deutsch, 723 F. Supp. 2d at 525-26 ("Plaintiffs have failed to rebut Novartis's plausible claim that the corporate decisions at issue were made from the company's corporate headquarters in New Jersey. Accordingly, because the relevant conduct at issue took place primarily in New Jersey, and not New York, New Jersey law on punitive damages is applicable under the New York choice of law analysis."); Talley, 2011 WL 2559974, at *4 ("The record demonstrates that the corporate decisions at issue regarding labeling and packaging, occurred in New Jersey"); Charles S. Irby v. Novartis Pharmaceuticals Corp., No. MID-L-1815-08, 278, 2011 WL 5835414 (Superior Court of New Jersey, Nov. 18, 2011) ("Plaintiff's claims stem from Defendant's business activities in New Jersey regarding the marketing, distributing, and selling of Zometa").

e. Which State has the Most Significant Relationship

Next, the court must determine, with reference to the factors in section 6(2) and the contacts in section 145(2) of the Restatement (Second), which state has the most significant relationship to the issue of punitive damages in this matter. Hataway, 830 S.W.2d at 59. "[T]he local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship under the principles stated in § 6 to the occurrence and the parties, in which event the local law of the other state will be applied." Restatement (Second) of Conflict of Laws § 146. Here, the parties agree North Carolina is where injury is alleged to have occurred. Accordingly, defendant must demonstrate that New Jersey has a more significant relationship to the issue of punitive damages than does North Carolina.

"The extent of the interest of each of the potentially interested states should be determined

on the basis, among other things, of the purpose sought to be achieved by their relevant local law rules and of the particular issue." Restatement (Second) of Conflict of Laws § 146, cmt. c. North Carolina's punitive damages law has the explicit purpose "to punish a defendant for egregiously wrongful acts and to deter the defendant and others from committing similar wrongful acts." N.C. Gen. Stat. § 1D-1. "Punitive damages are *never* awarded as compensation. They are awarded above and beyond actual damages, as punishment for the defendant's intentional wrong." Rhyne v. K-Mart Corp., 358 N.C. 160, 166, 594 S.E.2d 1, 6 (2004). Similarly, the purpose behind New Jersey's punitive damages statute, generally, is "to punish the defendant and to deter that defendant from repeating such conduct." N.J. Stat. Ann. § 2A:15-5.14(a). Further, "N.J.S.A. 2A:58C-5c is designed to effectuate the State's interest in punishing unlawful conduct." McDarby, 401 N.J. Super. At 93, 949 A.2d at 275. "In contrast, the purpose of compensatory damages is to make the individual plaintiff whole." Id., 401 N.J. at 91, 949 A.2d at 274.

Commentary to the Restatement (Second) emphasizes that "when the primary purpose of the tort rule involved is to deter or punish misconduct, the place where the conduct occurred has peculiar significance." Restatement (Second) of Conflicts § 145, cmt. e. See also id § 146, cmt. d ("If [the purpose of the rule of tort law involved] is to punish the tortfeasor and thus to deter others from following his example, there is better reason to say that the state where the conduct occurred is the state of dominant interest and that its local law should control than if the tort rule is designed primarily to compensate the victim for his injuries."). Courts, applying Restatement (Second) analysis, have chosen to apply the punitive damages law of the state in which the tortfeasor's allegedly wrongful conduct occurred. See Talley, 2011 WL 2559974, at *5 (applying the punitive damages law of New Jersey, where defendant's corporate decisions were made); Deutsch, 723 F.

Supp. 2d at 525 (similarly applying the punitive damages law of New Jersey, where defendant's corporate decisions were made); Aguirre Cruz v. Ford Motor Co., 435 F. Supp. 2d 701, 706 (W.D. Tenn. 2006) (applying Tennessee choice-of-law rules, namely the Restatement (Second) approach, and holding, "Michigan, as defendant's principal place of business and the place where the alleged misconduct occurred, has the most significant relationship to the issue of punitive damages").

Accordingly, where wrongful conduct here is alleged to have occurred at defendant's principal place of business, located in New Jersey, and where the purpose of both North Carolina and New Jersey punitive damages law is to *punish* and *deter* tortfeasors, rather than compensate victims, the court holds that New Jersey law applies to the issue of punitive damages. As to that issue, New Jersey has the most significant relationship under the principles stated in § 6 to the occurrence and the parties. The "occurrence" relevant for determination of punitive damages is conduct that would have occurred in New Jersey, namely defendant's decisions as to marketing, drug labeling, and notification. And where New Jersey is the location of defendant's principal offices, it has the most significant relationship with defendant of any interested state.

Applying New Jersey law to the issue of punitive damages conforms with the factors set forth in Restatement (Second) § 6, particularly factors (c), (d), (e), and (f). Defendant has a justified expectation to have New Jersey law determine whether its conduct in that state warrants punishment. In turn, plaintiffs, as North Carolina residents, have a justified expectation to have their compensation, if any, determined by the laws of the state in which they live and suffered the alleged injury. Further, the policy reflected in New Jersey's punitive damages law – to punish a defendant if warranted for misconduct within its border – is advanced through application of its punitive damages law. In contrast, North Carolina does not have as great an interest in punishing conduct that

occurred in another state. Finally, application of New Jersey law to the issue of punitive damages will promote certainty, predictability, and uniformity of result. Defendant has principal offices in New Jersey, and, pursuant to 28 U.S.C. § 1332(c)(1), is considered a citizen of that state. New Jersey is therefore most interested in regulating the conduct of its citizen and is best-suited to determine when such conduct warrants punitive damages.

For the foregoing reasons, defendant's motion to apply New Jersey law to the issue of punitive damages (DE # 46) is GRANTED.

C. Defendant's Motion *in Limine* to Exclude Adverse Drug Experience Reports (DE # 103)

On December 2, 2011, defendant filed motion *in limine*, requesting that the court exclude evidence concerning (1) adverse drug experience ("ADE") reports or aggregate numbers of ADE reports not substantially similar to the events alleged in this case and (2) ADE reports received by defendant after September 13, 1996, the date Mr. Brown commenced bisphosphonates therapy with Aredia. Defendant contends that any individual ADE report should be excluded under Federal Rules of Evidence 401-403, unless the particular ADE report at issue is substantially similar to the alleged events in this case. Defendant further argues that any probative value of one or more ADE reports would be substantially outweighed by the time and confusion involved in disputing the substantial similarity of the particular report. In addition, defendant maintains that ADE reports and collected numbers of such reports should be excluded as inadmissible hearsay. Finally, defendant argues that to the extent ADE reports are admitted, they must be limited to reports received by defendant prior to September 13, 1996, when Mr. Brown commenced his Aredia therapy.

Plaintiffs responded in opposition on December 15, 2011. As to the dissimilarities between Mr. Brown's condition and the experiences described in specific ADE reports sent to defendant,

plaintiffs argue that such dissimilarities effect the weight of the evidence, not admissibility. As to defendant's hearsay objection, plaintiffs respond that they would offer the reports as proof of defendant's notice, not for the truth of the matter asserted. Plaintiffs further direct the court's attention to opinion of the Western District of Kentucky, dated December 14, 2011, disposing of similar objections to introduction of ADE reports. See Mahaney ex rel. estate of Kyle v. Novartis Pharmaceuticals Corp., 835 F. Supp. 2d 299, 311 (W.D. Ky. 2011).

At motions hearing held February 3, 2012, the court took up defendant's objections to the ADE reports. First, as to the admissibility of aggregate numbers of ADE reports, the court signaled agreement with Mahaney. Where the parties have attempted to further litigate this issue, the court clarifies its ruling here. Plaintiffs' experts may reference the aggregate number of Zometa- and Aredia-related ADE reports to prove medical causation, insofar as they relied on it to form their opinions. See Mahaney, 835 F. Supp. 2d at 312. This ruling applies at least to plaintiffs' expert Dr. Marx, who will testify among other things as to general causation. Defendant may address on cross-examination dissimilarities between Mr. Brown's medical conditions and experiences and those referenced in the ADE reports. Id.

The court also ruled at hearing that specific ADE reports could be admitted to show notice on defendant, rather than for the truth of the matter asserted. Other courts have allowed admission of ADE reports to show notice on pharmaceutical manufacturers of a drug's side effects. See Mahaney, 835 F. Supp. 2d at 312; Hogan v. Novartis Pharmaceuticals Corp., 06 CIV. 0260 BMC RER, 2011 WL 1533467, at *13 (E.D.N.Y. Apr. 24, 2011); Bartlett v. Mut. Pharm. Co., Inc., 08-CV-358-JL, 2010 WL 3092649, at *1 (D.N.H. Aug. 2, 2010). The court has instructed the parties to submit, if desired, a proposed limiting instructing that would clarify for the jury that any ADE

report could not be considered for the truth of the matter asserted.

At hearing, the court requested further briefing as to limits on admissibility based on the date of a particular ADE report. Plaintiffs, in brief filed May 1, 2012, contend that they should be allowed to introduce or refer to individual reports dated on or before April 27, 2005, the date Mr. Brown was diagnosed with osteonecrosis of the jaw and ceased bisphosphonate treatment. Defendant maintains that the appropriate cut-off date should be either September 13, 1996, when Mr. Brown began Aredia therapy, or January 11, 2002, when he commenced Zometa therapy.

Plaintiffs' proffered date, April 27, 2005, is more compelling. Under relevant North Carolina law, a manufacturer of a product may be found liable, given satisfaction of certain preliminary conditions, if "the manufacturer . . . became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances." N.C. Gen. Stat. § 99B-5(a)(2). Thus, notice on defendant of adverse effects of its drugs would be relevant at least up until Mr. Brown ceased medication. See also Hogan, 2011 WL 1533467, at *13 (finding that notice can be established by "[i]ndividual reports and the total number of ONJ reports before June, 2005," at which point plaintiff's doctors temporarily halted the Zometa infusions because they concluded it was contributing to plaintiff's jaw condition). Accordingly, the court agrees with plaintiffs that the ADE reports received by defendant on or before April 27, 2005, the date Mr. Brown stopped taking Zometa, may be admitted for the purpose of showing notice on defendant.

Finally, the court is aware that other courts have required demonstration that a particular ADE report is "substantially similar" to a plaintiff's condition before allowing introduction of the

report to show notice on defendant. In Mahaney, for instance, the court held, "[i]f Plaintiff introduces specific ADE reports to show notice to NPC of Zometa's side effects, those reports must be substantially similar to the matter at hand. For substantial similarity, it is enough that the ADE report concern a patient suffering medical complications analogous to ONJ after taking Zometa or Aredia." Mahaney, 835 F. Supp. 2d at 312-13; see also Bartlett, 2010 WL 3092649, at *1 ("They need only be 'substantially similar'"); but see Hogan, 2011 WL 1533467, at *13 ("Individual reports and the total number of ONJ reports before June, 2005 can establish notice regardless of whether Hogan's jaw condition was not similar to any of the patients described in the report"). Where the parties have not made clear to the court the content or quantity of ADE reports at issue, nor presented any specific reports for review, the court declines at this time to set a standard of "substantial similarity." The level of similarity required, if any, will need to be determined in the context of trial.

D. Defendant's Motion *in Limine* to Exclude Evidence Based on Incorrect Legal Standards (DE # 114)

Defendant seeks to preclude plaintiffs from presenting evidence that would suggest that defendant had a duty to warn Mr. Brown's dentist, oral surgeon, periodontist, or health care providers other than his prescribing physicians, Drs. John Hunter and Birgit Arb, concerning any of the alleged risks related to Aredia or Zometa or any of the alleged preventive measures plaintiffs contend defendant ought to have warned about. Defendant argues that pursuant to North Carolina General Statute § 99B-5(c), defendant's duty to warn extends only to the prescribing physician, not to other medical personnel who later become involved with the care of the patient. Thus, defendant maintains, evidence of its failure to warn persons other than Mr. Brown's prescribing physicians is irrelevant under Federal Rule of Evidence 401 and unfairly prejudicial under Rule 403.

Section 99B-5(a) provides the appropriate starting point here:

> (a) No manufacturer or seller of a product shall be held liable in any product liability action for a claim based upon inadequate warning or instruction unless the claimant proves that the manufacturer or seller acted unreasonably in failing to provide such warning or instruction, that the failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought, and also proves one of the following:
>
> (1) At the time the product left the control of the manufacturer or seller, the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer or seller knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant.
>
> (2) After the product left the control of the manufacturer or seller, the manufacturer or seller became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

N.C. Gen. Stat. § 99B-5(a).

This subsection makes clear that the claimant has the burden of proving the manufacturer acted unreasonably in failing to provide warning or instruction. Further, the unambiguous language of § 99B-5(c) provides that if a pharmaceutical company gives adequate warning to claimant's prescribing physician, the manufacturer shall not be liable for failing to provide warning directly to claimant (unless the FDA requires such direct consumer warning)[4]:

> (c) Notwithstanding subsection (a) of this section, no manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires

[4] Plaintiffs do not contend here that the FDA requires direct consumer warning or instruction to accompany either Aredia or Zometa.

such direct consumer warning or instruction to accompany the product.

N.C. Gen. Stat. § 99B-5(c). The meaning of this subsection is clear: if defendant provided an adequate warning to the physicians that prescribed Mr. Brown's Aredia and Zometa, defendant shall not be liable in a products liability action for failure to warn.

However, the above analysis does not support a finding that evidence of defendant's failure to warn Mr. Brown, his dentist, oral surgeon, or other non-prescribing health care providers, is irrelevant. Pursuant to § 99B-5(a), plaintiffs have the burden of proving that defendant acted unreasonably in failing to provide warning. Therefore, evidence about defendant's failure to warn Mr. Brown's non-prescribing care providers, such as his dentist, oral surgeon, or periodontist, may be relevant if plaintiffs are able to show that defendant did not adequately warn Mr. Brown's prescribing physicians. It would be premature to order excluded any evidence regarding defendant's warnings to Mr. Brown's non-prescribing physicians. Accordingly, defendant's motion is DENIED, but the court will revisit this argument if particularized objections are made at trial.

E. Out-of-Court Statements by Panel Members (Schubert E-mails) (DE ## 111, 116)

Defendant, in its omnibus motion *in limine*, moves to exclude any out-of-court statements by members of two Advisory Boards, composed of physicians and oral surgeons, who provided comments regarding defendant's draft White Paper on the development of osteonecrosis of the jaw in patients using Zometa and Aredia.[5] In particular, defendant identifies e-mails from Dr. Mark Schubert, an oral surgeon, dated May 12, 2004, and May 28, 2004. Defendant argues that such out-of-court statements constitute inadmissible hearsay.

Plaintiffs respond that the e-mails are admissible as statements of an opposing party's agent,

[5] Defendant issued the White Paper in June 2004.

pursuant to Federal Rule of Evidence 801(d)(2)(D), or as records of a regularly conducted activity, pursuant to Rule 803(6). In the alternative, plaintiffs argue that the e-mails would not be offered for the truth of the matter asserted, although plaintiffs do not identify the purpose for which they would be offered.

Rule 801(d)(2)(D) provides that a statement is not hearsay if it is offered against an opposing party and "was made by the party's agent or employee on a matter within the scope of that relationship and while it existed." Fed. R. Evid. 801(d)(2)(D). The party offering the evidence must show that the declarant is an agent of the party-opponent and the scope of that agency. Womack v. Tierco Maryland Inc., 38 F. App'x 850, 857 (4th Cir. 2002) (citing United States v. Portsmouth Paving Corp., 694 F.2d 312, 321 (4th Cir. 1982)). "Agency is the fiduciary relationship that arises when one person (a 'principal') manifests assent to another person (an 'agent') that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act." Restatement (Third) of Agency § 1.01. See also Kernan v. One Washington Park Urban Renewal Associates, 154 N.J. 437, 453, 713 A.2d 411, 419 (1998) ("[a]n agency relationship is created when one party consents to have another act on its behalf, with the principal controlling and directing the acts of the agent"); State v. Weaver, 359 N.C. 246, 258, 607 S.E.2d 599, 606 (2005) ("Two essential elements of an agency relationship are: (1) the authority of the agent to act on behalf of the principal, and (2) the principal's control over the agent").

Here, plaintiffs have not provided evidence that Dr. Schubert acted as defendant's agent while serving on the Advisory Board. Plaintiffs have not shown that defendant exercised control over Dr. Schubert or any other members of the Advisory Boards, nor have they demonstrated that the members agreed to act on defendant's behalf. Accordingly, Rule 801(d)(2)(D) does not provide

a means of admission for the referenced Schubert e-mails.

Plaintiffs argue in the alternative that the Schubert e-mails and similar correspondence from Advisory Board members fall under the hearsay exception for records of regularly conducted activity. See Fed. R. Evid. 803(6). Rule 803(6) requires, among other things, that "the record was kept in the course of a regularly conducted activity of a business," and that "making the record was a regular practice of that activity." Fed. R. Evid. 803(6)(B), (C). "Reports and documents prepared in the ordinary course of business are generally presumed to be reliable and trustworthy for two reasons: First, businesses depend on such records to conduct their own affairs; accordingly, the employees who generate them have a strong motive to be accurate and none to be deceitful. Second, routine and habitual patterns of creation lend reliability to business records." Certain Underwriters at Lloyd's, London v. Sinkovich, 232 F.3d 200, 204-05 (4th Cir. 2000) (internal quotation marks omitted).

Yet plaintiffs have failed to establish that defendant's organization of Advisory Boards was a "regularly conducted activity," and they further fail to demonstrate that e-mail correspondence with Advisory Board members was a "regular practice of that activity." See New York v. Microsoft Corp., CIV A. 98-1233 (CKK), 2002 WL 649951, at *2 (D.D.C. Apr. 12, 2002). Accordingly, the Schubert e-mails do not satisfy the requirements of the Rule 803(6) hearsay exception.

Based on the foregoing, the court finds that the Schubert e-mails identified in the parties' memoranda do not fall under the Rule 801(d)(2)(D) non-hearsay exclusion or the Rule 803(6) hearsay exception. Where plaintiffs have not identified an applicable hearsay exception, the Schubert e-mails will not be admitted to prove the truth of the matter asserted. Fed. R. Evid. 801(c)(2), 802. However, should plaintiffs seek to introduce correspondence from Schubert or from

other members of the Advisory Boards for purposes other than to prove the truth of the matter asserted, argument shall be presented at the appropriate time to the court. Accordingly, final ruling on the admissibility of the Schubert e-mails or similar correspondence is reserved for trial.

F. Defendant's Motion *in Limine* to Exclude Evidence of Modifications of Labels (DE # 121)

Defendant moves to exclude any evidence that defendant modified the Zometa label in November 2007, or the Aredia label in December 2008. In support, defendant cites Federal Rule of Evidence 407, which provides:

> When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measure is not admissible to prove:
> - negligence;
> - culpable conduct;
> - a defect in a product or its design; or
> - a need for a warning or instruction.
>
> But the court may admit this evidence for another purpose, such as impeachment or–if disputed–proving ownership, control, or the feasibility of precautionary measures.

Fed. R. Evid. 407. "Rule 407 promotes an important policy of encouraging subsequent remedial measures." Werner v. Upjohn Co., Inc., 628 F.2d 848, 856 (4th Cir. 1980).

In Werner, the Fourth Circuit found reversible error where a district court allowed introduction of a defendant's 1975 alteration of a prescription drug warning in a trial regarding the adequacy of warning given in 1974. Id. at 853 ("This use of the 1975 warning clearly was impermissible and constitutes reversible error"). Other federal courts have similarly found that a pharmaceutical company's subsequent alternation of a drug's labeling is not admissible as evidence of defects in prior labeling. See Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254, 271 n. 10 (5th Cir. 2002); Gerber v. Hoffmann-La Roche Inc., 392 F. Supp. 2d 907, 919 (S.D. Tex. 2005). Indeed, defendant cites to recent opinions in which federal courts have found that labeling changes

for Zometa and Aredia in November 2007 and December 2008, respectively, fall within the protections of Rule 407. Mahaney ex rel. estate of Kyle v. Novartis Pharmaceuticals Corp., 835 F. Supp. 2d 299, 314 (W.D. Ky. 2011); Hogan v. Novartis Pharmaceuticals Corp., 06 CIV. 0260 BMC RER, 2011 WL 1336566, at *4 (E.D.N.Y. Apr. 6, 2011).

In accordance with the above, the court finds that evidence of the 2007 and 2008 labeling changes for Zometa and Aredia is inadmissible for those prohibited purposes set forth in Rule 407, namely to prove negligence, culpable conduct, a defect in a product or its design, or a need for a warning or instruction. Fed. R. Evid. 407. The court may however admit such evidence for a purpose permitted under Rule 407, such as impeachment. Id. Before doing so, counsel must approach the bench and identify for the court intended evidentiary purpose. See Mahaney, 835 F. Supp. 2d at 314.

CONCLUSION

As set forth above, the court herein orders the following:

1. Defendant's motion to seal (DE # 132) is GRANTED IN PART and HELD IN ABEYANCE IN PART. The clerk of court is DIRECTED to seal those documents provisionally filed under seal at docket entries 125 and 127. The court reserves for future determination whether to seal docket entry numbers 126 and 128 through 131;

2. Plaintiffs' motion to seal their response to defendant's omnibus motion *in limine* and attachments thereto (DE # 146) is DENIED AS MOOT. The clerk of court is directed to unseal the document provisionally filed under seal at entry number 145 and all attachments thereto;

3. Plaintiffs' motion to seal their objections to the magistrate judge's M&R (DE # 156) is

GRANTED IN PART. The clerk of court is DIRECTED to maintain under seal docket entries 155, 155-5, and 155-6. However, plaintiffs shall file within fourteen (14) days of entry of this order a redacted version of their objections to the M&R, redacting only those portions pertaining to the discussed deposition excerpts. Further, the clerk of court is DIRECTED to unseal docket entry numbers 155-1 through 155-4;

4. Defendant's motion to apply New Jersey law to the issue of punitive damages (DE # 46) is GRANTED;

5. As set forth more particularly above, defendant's motion *in limine* to exclude evidence concerning dissimilar ADE reports (DE # 103) is GRANTED IN PART AND DENIED IN PART. Plaintiffs' experts may reference the aggregate number of ADE reports to prove medical causation, insofar as they relied on it to form their opinions. Specific ADE reports received by defendant on or before April 27, 2005 may be admitted to show notice on defendant, not to prove the truth of the matter asserted;

6. Defendant's motion *in limine* to exclude evidence based on incorrect legal standards (DE # 114) is DENIED;

7. Defendant's request to exclude comments of Dr. Schubert or other members of Advisory Boards, referenced in defendant's omnibus motion *in limine* (DE # 116), is GRANTED IN PART. The Schubert e-mails will not be admitted to prove the truth of the matter asserted. However, should plaintiffs seek to introduce correspondence from Schubert or from other members of the Advisory Boards for purposes other than to prove the truth of the matter asserted, argument shall be presented at the appropriate time to the court; and

8. Defendant's motion *in limine* to exclude evidence of its subsequent knowledge or conduct

(DE # 121) is GRANTED IN PART.

SO ORDERED, this the 26th day of July, 2012.

LOUISE W. FLANAGAN
United States District Judge