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

BARBARA BOWLES, Plaintiff,	:	
v.	:	Case No. 3:12-cv-145
NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	:	JUDGE WALTER H. RICE

DECISION AND ENTRY SUSTAINING IN PART AND OVERRULING IN PART DEFENDANT'S *DAUBERT* MOTION TO EXCLUDE CAUSATION TESTIMONY OF PLAINTIFF'S EXPERT WITNESSES (DOC. #34); SUSTAINING IN PART AND OVERRULING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT (DOC. #36)

Plaintiff Barbara Bowles alleges that she developed osteonecrosis of the jaw ("ONJ") after being infused with Aredia® and Zometa®, nitrogenous bisphosphonate drugs manufactured by Novartis Pharmaceuticals Corporation ("NPC"). She filed suit against NPC, alleging claims of strict product liability, negligent manufacture, negligent failure to warn, breach of express warranty, and breach of implied warranty. Doc. #1. Her Amended Complaint drops the negligent manufacture claim, and adds claims under the Ohio Products Liability Act, Ohio Revised Code § 2307.71, *et seq.* Doc. #59. This matter is currently before the Court on Defendant NPC's *Daubert* Motion to Exclude Causation Testimony of

Plaintiff's Expert Witnesses, Doc. #34, and on Defendant NPC's Motion for Summary Judgment, Doc. #36.

I. Background and Procedural History

After being diagnosed with multiple myeloma in 1997, Barbara Bowles's oncologists prescribed Aredia®, a nitrogenous bisphosphonate drug. Aredia® and its successor drug, Zometa®, are both produced and marketed by NPC. They are approved by the Food and Drug Administration ("FDA"), and have proven very effective in preventing bone pain, fracture and other skeletal complications in patients with cancer that has metastasized to the bone. It is standard practice to prescribe these drugs to certain cancer patients.

Bowles received monthly infusions of Aredia® from August of 1997 until September of 2006. She also received two doses of Zometa®, one in April of 2005, and one in March of 2007. Bowles alleges that as a result of taking these drugs, she developed osteonecrosis of the jaw ("ONJ"), a painful, debilitating, and disfiguring condition involving the death of part of the jawbone. She first exhibited symptoms in 2001, after having tooth #31 extracted. The extraction site would not heal, and she experienced pus drainage, an unpleasant odor, pain, bone spurs and fragments. She stopped taking Aredia® in 2006, after being diagnosed with ONJ.

On September 4, 2007, Bowles, a resident of Dayton, Ohio, filed suit against NPC in the United States District Court for the District of Columbia. Her

Complaint included common law claims of strict product liability, negligent manufacture, negligent failure to warn, breach of express warranty, and breach of implied warranty. Her case was one of hundreds of similar cases filed across the country, all alleging that NPC knew or should have known of the risk that Aredia® and Zometa® would cause ONJ, and failed to provide timely and adequate notice of that risk to the public and to health care professionals. The Judicial Panel on Multi-District Litigation consolidated the cases for pretrial purposes, and they were divided into several litigation "waves." *In re Aredia® and Zometa® Products Liability Litigation*, No. 3:06-MD-1760 (M.D. Tenn.).

In January of 2012, Bowles's case was remanded to the United States District Court for the District of Columbia and, in May of 2012, it was transferred to the United States District Court for the Southern District of Ohio. On November 13, 2012, NPC filed a Motion for Summary Judgment. Doc. #36. In connection with that motion, NPC also filed a *Daubert* Motion to Exclude Causation Testimony of Plaintiff's Expert Witnesses. Doc. #34.

In reviewing the pending motions, the Court noted that the parties agreed that Ohio law governed the claims, which are subject to the Ohio Products Liability Act ("OPLA"), Ohio Revised Code §§ 2307.71-2307.80. Because the OPLA abrogates all common law product liability claims, Ohio Revised Code § 2307.71(B), the Court ordered Plaintiff to file an Amended Complaint, reasserting her claims under the OPLA. Doc. #58.

Bowles filed her Amended Complaint on July 29, 2013. Doc. #59. Her Amended Complaint asserts the following claims: (1) strict liability; (2) negligence -- design defect; (3) negligence – failure to warn; (4) breach of express warranty; (5) breach of implied warranty; (6) inadequate warning under Ohio Revised Code § 2307.76(A); (7) nonconformance with manufacturer's representation under Ohio Revised Code § 2307.77; and (8) punitive and exemplary damages under Ohio Revised Code § 2307.80.

Before addressing the merits of these claims, the Court turns first to NPC's *Daubert* Motion to Exclude Causation Testimony of Plaintiff's Expert Witnesses, Doc. #34.

II. Defendant's *Daubert* Motion to Exclude Causation Testimony of Plaintiff's Expert Witnesses (Doc. #34)

Citing Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Defendant NPC has moved to exclude the testimony of Plaintiff's expert witnesses concerning the issue of specific causation, *i.e.*, whether Plaintiff's use of Aredia® and Zometa® caused her to develop ONJ. Doc. #34. More specifically, NPC seeks to exclude specific causation opinions of Plaintiff's treating dentists and oral surgeons – Dr. Robert Mazzola, Dr. Michael Dahm, Dr. Ganesh Loganathan, and Dr. Reza Miremadi. It also seeks to exclude the specific causation opinion of Plaintiff's retained expert witness, Dr. Talib Najjar.

Federal Rule of Evidence 702 governs the admissibility of expert witness testimony. It states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In *Daubert*, the Supreme Court assigned the trial judge a "gatekeeping" function. The trial judge must ensure that the expert witness's testimony "both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. at 597. The court need not hold a hearing, but "is required to make an initial assessment of the relevance and reliability of the expert testimony." *Greenwell v. Boatwright*, 184 F.3d 492, 498 (6th Cir. 1999).

The Court finds that there is no need for a hearing because there is sufficient evidence in the record to allow the Court to determine whether the proposed expert witness testimony is relevant and reliable. For the reasons set forth below, the Court SUSTAINS NPC's motion to exclude specific causation testimony by Plaintiff's treating physicians, but OVERRULES the motion with respect to Dr. Najjar.

A. Treating Physicians

As the Sixth Circuit noted in *Gass v. Marriott Hotel Services, Inc.*, 558 F.3d 419 (6th Cir. 2009):

> Generally, a treating physician may provide expert testimony regarding a patient's illness, the appropriate diagnosis for that illness, and the cause of the illness. *See Fielden v. CSX Transp., Inc.*, 482 F.3d 866, 870 (6th Cir.2007). However, a treating physician's testimony remains subject to the requirement set forth in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), that an expert's opinion testimony must "have a reliable basis in the knowledge and experience of his discipline." *Id.* at 592, 113 S.Ct. 2786.

Id. at 426.

There is a distinction between diagnosing a medical condition and determining its cause. Typically, specific causation is determined through the use of a differential etiology, whereby all possible causes are considered and then ruled out one by one until the "most likely cause" is identified. Relevant questions include:

> (1) Did the expert make an accurate diagnosis of the nature of the disease? (2) Did the expert reliably rule in the possible causes of it? (3) Did the expert reliably rule out the rejected causes? If the court answers "no" to any of these questions, the court must exclude the ultimate conclusion reached.

Tamraz v. Lincoln Elec. Co., 620 F.3d 665, 673-74 (6th Cir. 2010).

NPC argues that Plaintiff's treating dentists and oral surgeons are not qualified to testify about whether Plaintiff's use of Aredia® and Zometa® caused her to develop ONJ. This argument is largely moot with respect to Dr. Mazzola, Dr. Dahm, and Dr. Loganathan since none professes to have any opinion about

specific causation. Although Dr. Miremadi opines that Plaintiff's ONJ was caused by her use of NPC's drugs, the Court finds that his opinion is not admissible because it is not based on a reliable methodology.

1. Drs. Mazzola, Dahm, Loganathan

Dr. Mazzola is a general dentist who has treated Plaintiff since 1996. He has admitted that he is not an expert in ONJ, did not personally diagnose Plaintiff with ONJ, and did not conduct a differential etiology to rule out potential causes of her jaw problems. Mazzola Dep. at 36, 79-80 (Ex. 1 to Doc. #34). Dr. Dahm is also a general dentist who treated Plaintiff many years before she was diagnosed with cancer or with ONJ. There is no evidence that he has any opinion regarding the cause of her ONJ. Dahm Dep. at 12-13 (Ex. 4 to Doc. #34). Dr. Loganathan, a general dentist, treated Plaintiff on several occasions. He admits that he is not an expert on ONJ, and has never diagnosed it. Moreover, he has no opinion on the cause of Plaintiff's ONJ. Loganathan Dep. at 30-32 (Ex. 5 to Doc. #34).

Certainly, these three treating dentists can testify as to Plaintiff's "symptoms, tests, diagnosis and treatment, as to what they did in response to [Plaintiff's] condition and as to what they would have done differently, if anything, had they known of any additional warnings." *In re: Aredia and Zometa Products Liability Litigation*, No. 3:06-md-1760, 2009 WL 2496886, at *3 (M.D. Tenn. Aug. 13, 2009). However, absent any evidence that they conducted a differential etiology (or, in this case, even made an attempt to determine the cause of

Plaintiff's jaw problems), the Court finds that they are not qualified to offer an opinion about specific causation.

2. Dr. Miremadi

Dr. Miremadi, a board-certified oral surgeon and maxillofacial surgeon, treated Plaintiff from 2006-2009. He is very familiar with the relevant literature on the alleged association between exposure to bisphosphonate drugs and the development of ONJ. Miremadi Dep. at 16-17 (Ex. H to Doc. #48). He frequently lectures on the treatment of patients with bisphosphonate-induced ONJ, and is familiar with the various risk factors for developing ONJ. *Id.* at 17-18, 47-48. In July of 2006, during the course of his treatment of Plaintiff, Dr. Miremadi diagnosed her with ONJ. Based on his knowledge and experience, he believes that her ONJ was caused by or exacerbated by her use of Aredia®. Miremadi Dep. at 107 (Ex. 3 to Doc. #34).

NPC concedes that Dr. Miremadi is generally qualified to testify as an expert witness on the subject of ONJ. NPC argues, however, that Dr. Miremadi's opinion concerning specific causation in this case is based on a flawed and unreliable methodology. Dr. Miremadi testified that he did not remember whether he conducted a differential etiology, considering all possible risk factors and then ruling them out. *Id.* at 71.

Dr. Miremadi admitted that he could not have considered a pathology report that came back after he had made his diagnosis. *Id.* at 84-85. He further admitted that although chemotherapy drugs may also cause ONJ, he was unaware

that Plaintiff had been prescribed any such drugs. *Id.* at 62. He did not review her previous dental history or her oncological records. *Id.* at 72.

NPC maintains that Dr. Miremadi essentially concluded that because Plaintiff took Aredia® and then developed ONJ, Aredia® must have been the cause of the injury. NPC likens this case to *Tamraz*, in which the court excluded the expert witness testimony of a treating physician who opined that the plaintiff's Parkinson's disease was caused by his exposure to magnesium. The doctor's opinion was based solely on scientific literature that suggested there may be a possible link between the two. The court found that this "hypothesis" was too speculative to survive scrutiny under Rule 702. *Tamraz*, 620 F.3d at 671-72.

In this case, based on his knowledge and experience, Dr. Miremadi may have a strong suspicion that Plaintiff's ONJ developed as a result of her use of Aredia®. However, his opinion is not backed up by reliable methodology. Notably, it is not clear that he conducted any differential etiology at all. There is no evidence that Dr. Miremadi reliably ruled in all possible causes of Plaintiff's ONJ, or that he reliably ruled out any alternative causes.

Because Dr. Miremadi's opinion regarding specific causation is scientifically unreliable, it is inadmissible. As with the other treating physicians, he may, however, testify about Plaintiff's "symptoms, tests, diagnosis and treatment, as to what [he] did in response to [Plaintiff's] condition and as to what [he] would have done differently, if anything, had [he] known of any additional warnings." *In re: Aredia and Zometa Products Liability Litigation*, 2009 WL 2496886, at *3.

B. Retained Expert

Dr. Talib Najjar is a board-certified oral pathologist and oral maxillofacial surgeon, retained by Plaintiff as an expert witness on the question of specific causation. Dr. Najjar is a specialist in diseases of the jaw, has researched ONJ in rats, and has treated several patients with bisphosphonate-induced ONJ. In his report, he concludes, to a reasonable degree of medical certainty, that Plaintiff developed ONJ as a result of her treatment with Aredia® and Zometa®. Najjar Report at 3 (Ex. 6 to Doc. #34). NPC asks the Court to exclude his specific causation testimony.

Citing *Foster v. Legal Sea Foods, Inc.*, No. CCB-03-2512, 2008 WL 2945561, at *10 (D. Md. July 25, 2008), and *Grimes v. Hoffman-LaRoche, Inc.*, 907 F. Supp. 33, 38 (D.N.H. 1995), NPC argues that establishing general causation, *i.e.*, that bisphosphonate drugs cause ONJ, is a prerequisite to establishing specific causation, *i.e.*, that bisphosphonate drugs caused ONJ in Sheffer's case. NPC maintains that because Dr. Najjar has admitted that the causal relationship between the occurrence of ONJ and Zometa® has not yet been scientifically proven through controlled studies, he should not be permitted to testify that this drug caused ONJ in Bowles's case. Najjar 3/17/09 Dep. at 184 (Ex. 7 to Doc. #34).

Nevertheless, the fact that the causal link between the drugs and ONJ has not yet been conclusively established *through controlled studies* does not mean that Plaintiff cannot establish general causation. Dr. Najjar testified that, despite

the lack of controlled studies, there is a "strong association" between bisphosphonate drugs and ONJ. 3/17/09 Najjar Dep. at 284. Moreover, the MDL Court has already determined that genuine issues of material fact exist concerning general causation. *In re: Aredia and Zometa Prods. Liability Litigation*, No. 3:06-md-1760, Docs. ##2763, 2764 (M.D. Tenn. Aug. 9, 2009).[1] Under these circumstances, the absence of controlled studies conclusively establishing general causation does not provide any basis for excluding Dr. Najjar's specific causation opinion.

NPC further argues that Dr. Najjar's opinion is based on unreliable methodology. According to NPC, Dr. Najjar's differential etiology is flawed in that he admitted that he could not rule out multiple myeloma, bacterial infection, and osteomyelitis as possible causes of Plaintiff's jaw problems. Najjar 9/14/11 Dep. at 31, 43 (Ex. 9 to Doc. #34). His failure to conclusively rule out every possible alternative cause does not necessarily render his testimony deficient under *Daubert*. *See Davids v. Novartis Pharm. Co.*, 857 F. Supp.2d 267, 278 (E.D.N.Y. 2012) (citing *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001)). Notably, Dr. Najjar did specifically rule out many other possible causes of ONJ in Bowles's case, including "metastatic breast cancer, fibrosseous lesions, florid osseous dysplasia, osteoporosis, osteomyelitis, prolonged corticosteroid and

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[1] The MDL Court's ruling constitutes the "law of the case." Under the "law of the case" doctrine, this court cannot reconsider issues decided at an earlier stage of the proceedings. *McKenzie v. BellSouth Telecommunications, Inc.*, 219 F.3d 508, 512 (6th Cir. 2000).

phosphorous exposure . . . dental, periodontal conditions, chemotherapy, anemia, malnutrition, a trauma." Najjar Report at 3.

Based on the evidence presented, the Court finds that Dr. Najjar is qualified to offer an opinion regarding specific causation, and that his opinion is based on reliable methodology, *i.e.*, a differential etiology. Any disagreements over the sufficiency of that etiology go to the weight of his testimony, not to its admissibility. *Davids*, 857 F. Supp.2d at 279. The Court therefore overrules Defendant's motion to exclude Dr. Najjar's testimony on the issue of specific causation.

III. Defendant's Motion for Summary Judgment

A. Summary Judgment Standard

Summary judgment must be entered "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The moving party always bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of the record which it believes demonstrate the absence of a genuine issue of material fact. *Id.* at 323; *see also Boretti v. Wiscomb*, 930 F.2d 1150, 1156 (6th Cir. 1991).

"Once the moving party has met its initial burden, the nonmoving party must present evidence that creates a genuine issue of material fact making it necessary

to resolve the difference at trial." *Talley v. Bravo Pitino Rest., Ltd.*, 61 F.3d 1241, 1245 (6th Cir. 1995); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient to "simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Rule 56 "requires the nonmoving party to go beyond the [unverified] pleadings" and present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324. "The plaintiff must present more than a scintilla of evidence in support of his position; the evidence must be such that a jury could reasonably find for the plaintiff." *Michigan Prot. & Advocacy Serv., Inc. v. Babin*, 18 F.3d 337, 341 (6th Cir. 1994).

Summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Summary judgment will not lie if the dispute about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248. In determining whether a genuine dispute of material fact exists, a court must assume as true the evidence of the nonmoving party and draw all reasonable inferences in favor of that party. *Id.* at 255. If the parties present conflicting evidence, a court may not decide which evidence to believe. Credibility

determinations must be left to the fact-finder. 10A Wright, Miller & Kane, *Federal Practice and Procedure* Civil 3d § 2726 (1998).

In determining whether a genuine dispute of material fact exists, a court need only consider the materials cited by the parties. Fed. R. Civ. P. 56(c)(3). "A district court is not . . . obligated to wade through and search the entire record for some specific facts that might support the nonmoving party's claim." *InterRoyal Corp. v. Sponseller*, 889 F.2d 108, 111 (6th Cir. 1989), *cert. denied*, 494 U.S. 1091 (1990). If it so chooses, however, the court may also consider other materials in the record. Fed. R. Civ. P. 56(c)(3).

B. Analysis

Plaintiff originally filed suit in the United States District Court for the District of Columbia, and asserted common law claims of: (1) strict product liability; (2) negligent manufacture; (3) negligent failure to warn; (4) breach of express warranty; and (5) breach of implied warranty. Because Plaintiff lives in Ohio and the alleged injury was suffered in Ohio, the case was transferred here.

The parties agree that Ohio law governs Plaintiff's claims, which are subject to the Ohio Products Liability Act ("OPLA"). The OPLA allows only four theories of recovery: (1) manufacturing defect, Ohio Rev. Code § 2307.74; (2) design defect, Ohio Rev. Code § 2307.75; (3) inadequate warning or instruction, Ohio Rev. Code § 2307.76; and (4) non-conformance with manufacturers' representations, Ohio Rev. Code § 2307.77.

In its Motion for Summary Judgment, NPC argues that even if Plaintiff had properly pled her causes of action under the OPLA instead of under the common law, summary judgment was still warranted on all of Plaintiff's claims. On July 8, 2013, the Court ordered Plaintiff to file an Amended Complaint, reasserting her claims under the OPLA. Doc. #58.

Rather than replace her common law claims with statutory claims under the OPLA, Plaintiff has inexplicably reasserted each of her original common law claims, except for her claim of negligent manufacture. She has also added two new claims under the OPLA -- a claim of inadequate warning, under Ohio Revised Code § 2307.76(A), and a claim of nonconformance with the manufacturers' representations, under Ohio Revised Code § 2307.77. She also seeks punitive and exemplary damages under Ohio Revised Code § 2307.80. Am. Compl., Doc. #59.

The Court gave NPC the opportunity to modify the pending Motion for Summary Judgment in light of the Amended Complaint. Doc. #58. NPC has notified the Court that no modifications are needed. Doc. #61. Accordingly, the Court will address the merits of each of Plaintiff's claims, as asserted in the Amended Complaint.

1. Common Law Claims

Effective April 7, 2005, the OPLA "abrogate[d] all common law product liability claims or causes of action." Ohio Rev. Code § 2307.71(B). *See Wimbush v. Wyeth*, 619 F.3d 632, 637 (6th Cir. 2010) ("Strict liability for manufacturers and suppliers is codified by the Ohio Products Liability Act."); *Miller v. ALZA Corp.*,

759 F. Supp.2d 929, 943-44 (S.D. Ohio 2010) (holding that common law claims of negligence, breach of express warranty, and breach of implied warranty are abrogated by the OPLA).

Accordingly, the Court SUSTAINS NPC's Motion for Summary Judgment on the following common law causes of action: (1) Count I: Strict Liability; (2) Count II: Negligence - Design Defect; (3) Count III: Negligence - Failure to Warn; (4) Count IV: Breach of Express Warranty; and (5) Count V: Breach of Implied Warranty.

2. OPLA Claims

a. Failure to Warn

Count VI of the Amended Complaint asserts a "failure to warn" claim under Ohio Revised Code § 2307.76(A)(1). That statute provides that a product is defective due to inadequate warning if, when it left the manufacturer's control, both of the following applied:

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages; [and]
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76(A)(1).

A product is defective due to inadequate *post-marketing* warning if, when it left the manufacturer's control, both of the following applied:

> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages; [and]
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> (b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Ohio Rev. Code § 2307.76(A)(2).

To succeed on a "failure to warn" claim, a plaintiff must prove: "(1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury that is proximately caused by the breach." *Miller*, 759 F. Supp.2d at 934 (quoting *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514 (6th Cir. 2003)).

NPC argues that it is entitled to summary judgment on this claim because Plaintiff cannot show that NPC breached a duty to warn against reasonably foreseeable risks, or that her injury was proximately caused by the breach. Based on the evidence presented, the Court finds that genuine issues of material fact preclude summary judgment on this "failure to warn" claim.

i) Breach of Duty

NPC maintains that it issued timely and adequate warnings concerning the risk of bisphosphonate-induced ONJ. According to NPC, the first case of bisphosphonate-induced ONJ was not reported until December of 2002. Ex. 22 to

Doc. #36. It was not until September of 2003 that Dr. Richard Marx published the first case reports. R.E. Marx, *Pamidronate (Aredia) and Zoledronate (Zometa) Induced Avascular Necrosis of the Jaws: A Growing Epidemic*, 61 J. Oral Maxillofacial Surg. 1115 (2003). That same month, NPC voluntarily changed its drug labels to note that cases of ONJ had been reported. The label revision stated that ONJ "has other well documented risk factors. It is not possible to determine if these events are related to Zometa or other bisphosphonates, to concomitant drugs or other therapies." Ex. 31 to Doc. #36.

NPC revised its labels again in February of 2004 to note that because most cases of bisphosphonate-induced ONJ appeared to have been related to a dental procedure, dental surgery was not advisable. Ex. 33 to Doc. #36. In September of 2004, NPC again revised the labels to state that patients being treated with bisphosphonates "should avoid invasive dental surgery." Ex. 34 to Doc. #36. That same month, NPC sent letters to doctors warning of the risk of bisphosphonate-induced ONJ, and in May of 2005, NPC sent similar letters to dentists and oral surgeons. Exs. 35 and 37 to Doc. #36.

Plaintiff denies that these warnings were timely or adequate. A 1981 study involving rats had shown a connection between bisphosphonates and ONJ. Ex. 23 to Vecchione Decl. Moreover, at least six cases of ONJ were allegedly reported during the clinical trials of Aredia®. Exs. 26 and 27 to Vecchione Decl. Plaintiff therefore maintains that NPC should have identified the risk as early as 1991.

In "Wave I" of the multi-district litigation, the MDL Court determined that genuine issues of material fact preclude summary judgment on the issues of general causation and warning adequacy. It found that there are genuine factual disputes concerning what NPC knew or should have known, and when, and whether the letters sent to doctors and dentists timely and adequately conveyed information about the risk of developing ONJ. *In re Aredia and Zometa Prods. Liability Litigation*, No. 3:06-md-1760, Docs. #2764, 2767 (M.D. Tenn. Aug. 13 2009). Again, this constitutes the law of the case. Because the issues concerning breach of duty in this case are identical to those in the "Wave I" cases, the Court sees no basis for disturbing the ruling of the MDL court.

There is, however, one Ohio-specific issue raised by the parties that was not addressed by the MDL court. The OPLA provides that:

> An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction *to the physician or other legally authorized person who prescribes or dispenses that ethical drug* for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

Ohio Rev. Code § 2307.76(C) (emphasis added). Since this statute refers only to physicians or others who prescribe or dispense the drug in question, there is some question about whether NPC also had a duty to warn dentists and oral surgeons of the risks of bisphosphonate-induced ONJ.[2]

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[2] Although NPC did eventually send warning letters to dentists and oral surgeons, it did not do so until May of 2005.

Plaintiff notes that Restatement (Third) of Torts provides:

> A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing *and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings*. . .

Restatement (Third) of Torts: Prod. Liab. § 6(d)(1) (1998) (emphasis added). Plaintiff maintains that because bisphosphonate-induced ONJ is often triggered by invasive dental procedures, and because dentists and oral surgeons are in the best position to reduce the risk of harm, drug manufacturers have a duty to warn them of the relevant risks.

NPC notes that Ohio has not expressly adopted this section of the Restatement (Third) of Torts. Even so, Ohio Revised Code § 2307.76(A) refers to the failure to provide "the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm."

In the Court's view, the question of whether the manufacturer exercised "reasonable care" encompasses both the *content* of that warning and the *method* by which the manufacturer disseminates that warning. *See*, *Seley v. G.D. Searle & Co.*, 67 Ohio St.2d 192, 198, 423 N.E.2d 831, 837 (Ohio 1981) ("The fact finder may find a warning to be unreasonable, hence inadequate, in its factual content, its expression of the facts, or the method or form in which it is

conveyed."); *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 853 (10th Cir. 2003) (noting that one of the factors to be considered in determining whether a warning is adequate is what means were used to convey it). In determining whether the manufacturer exercised "reasonable care" in issuing a warning, a jury could find that, because bisphosphonate-induced ONJ is often triggered by invasive dental procedures, NPC had a duty to warn not only the prescribing physicians, but also the dental care providers who are, arguably, in an even better position to prevent the alleged harm.[3]

For the reasons set forth above, and those expressed by the MDL court in the "Wave I" cases, the Court concludes that genuine issues of material fact preclude summary judgment on the question of whether NPC breached its duty to provide timely and adequate warnings concerning the risk of bisphosphonate-induced ONJ.

ii) Proximate Cause

NPC also argues that Plaintiff has failed to produce sufficient evidence that the alleged failure to warn proximately caused her injury. In *Seley*, the Ohio

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[3] The question of whether a manufacturer exercised reasonable care in issuing a warning is distinct from the question of whether a manufacturer has discharged its duty to warn by providing an adequate warning to a learned intermediary. Therefore, the fact that the "learned intermediary" defense, codified in Ohio Revised Code § 2307.76(C), appears to apply only when a warning is given to the *prescribing physician*, does not mean that, under certain circumstances, a manufacturer's *duty to warn* may extend to other health care professionals as well. The Court expresses no opinion, at this juncture, about whether the "learned intermediary" defense could be extended to apply to warnings given to health care providers other than the prescribing physician.

Supreme Court explained that proximate cause involves two sub-issues: "(1) whether lack of adequate warnings contributed to the plaintiff's ingestion of the drug, and (2) whether ingestion of the drug constitutes a proximate cause of the plaintiff's injury." 67 Ohio St.2d at 200, 423 N.E.2d at 838. NPC argues that Plaintiff's claim is deficient in both respects.

NPC first argues that Plaintiff cannot prove that the lack of an adequate warning contributed to her use of Aredia® and Zometa®. Under Ohio law, it is presumed that if an adequate warning is given, it will be read and heeded. However, where no warning is given, or where the warning given is inadequate, a rebuttable presumption arises that the failure to adequately warn was a proximate cause of the plaintiff's use of the drug. *Id.* That presumption may be rebutted by proof that "an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug or as to whether to monitor the patient thereafter." *Id.* at 201, 423 N.E.2d at 838. Where a treating physician unequivocally testifies that an adequate warning would not have altered the course of treatment, summary judgment is warranted because there is no proximate cause between the lack of an adequate warning and the use of the drug. *Miller*, 759 F. Supp.2d at 936.

In this case, Plaintiff received Aredia® from 1997 until 2006, and received a dose of Zometa® in 2007. It is undisputed that NPC issued no warnings concerning the risk of ONJ until September of 2003. Moreover, the MDL Court has found genuine issues of material fact concerning whether the warnings given

thereafter were adequate, and this is the law of the case. Plaintiff is, therefore, entitled to the benefit of the presumption that the failure to adequately warn was a proximate cause of her use of the drugs. The question is whether NPC has successfully rebutted that presumption.

NPC argues that Plaintiff has presented no evidence that her treating health care professionals would have done anything differently if NPC had issued different or earlier warnings about the risks associated with Aredia® and Zometa®. Dr. Gary Nicholson, Plaintiff's oncologist from 1997 through 2005, testified that even if he had known of the risk of ONJ, he still would have prescribed Aredia.® Nicholson Dep. at 96 (Ex. 17 to Doc. #36). Likewise, oncologist Satheesh Kathula, M.D., continued to prescribe Aredia® for Plaintiff in 2005 and 2006 even after knowing the risks. Exs. ##105 and 106 to Doc. #36. He testified that if the benefits of the drug outweigh the side effects, he recommends that the patient take it. Kathula Dep. at 47 (Ex. 11 to Doc. #36).

The testimony of Plaintiff's oncologists is not necessarily dispositive. Because the onset of Plaintiff's ONJ was allegedly triggered by the extraction of tooth #31 in 2001, the question is not only whether her oncologists would have prescribed the drugs even knowing of the risk, but also whether her dentists and oral surgeons would have changed their course of treatment had they known of the risk of ONJ.

In a similar case, the MDL court held that the plaintiff could survive summary judgment by showing that any of the health care professionals, "not

simply the prescriber, would have behaved differently. Given additional knowledge, Plaintiff's oncologist might still have prescribed the drug, but *Plaintiff himself and/or Plaintiff's dentist or oral surgeon* might have behaved differently." The court found genuine issues of material fact concerning whether different warnings would have averted the injury. *In re Aredia and Zometa Products Liability Litigation*, No. 3:06-md-1760, 2009 WL 2497692, at *2 (M.D. Tenn. Aug. 13, 2009) (emphasis added).

This case is analogous. Dr. Nicholson testified that, had he known of the risks of ONJ, he still would have prescribed Aredia®, but would have adhered to any new guidelines, "like duration of treatment probably would be shorter." Nicholson Dep. at 96. Plaintiff maintains that because new guidelines also recommend that patients taking bisphosphonate drugs avoid invasive dental procedures, it can be inferred that, Dr. Nicholson would not have recommended that Dr. Mazzola extract tooth #31 before she began chemotherapy.

Plaintiff points out that in 2006 and in 2008, after NPC issued warnings about the risk of bisphosphonate-induced ONJ, Dr. Mazzola advised against extracting two *other* teeth, based on her prior use of Aredia®. Mazzola Dep. at 72-75 (Ex. 3 to Doc. #47). She argues that it can be inferred that, had the same warnings been available in 2001, Dr. Mazzola would not have extracted tooth #31.

NPC notes, however, that Dr. Mazzola testified that because tooth #31 was so deeply decayed, a root canal was not a viable option. Mazzola Dep. at 62 (Ex. 68 to Doc. #36). Therefore, according to NPC, even if adequate warnings existed,

it would not have made any difference in Plaintiff's treatment plan. NPC maintains that this case is akin to *Zimmerman v. Novartis Pharmaceuticals Corp.*, 287 F.R.D. 357, 361-62 (D. Md. 2012). There, because the dentist testified that extraction was the only available option, the court granted summary judgment in favor of NPC, finding that the plaintiff was unable to establish that the failure to warn against invasive dental procedures was the proximate cause of her injury. *See also Eberhart v. Novartis Pharm. Corp.*, 867 F. Supp.2d 1241, 1256 (N.D. Ga. 2011) (finding no causal link where, even though plaintiff said she would have refused extractions had she known of the risk of ONJ, her dentist testified that no other treatment options were available).

In the Court's view, Plaintiff's case is factually distinguishable from *Zimmerman* and *Eberhart* in one important respect. Dr. Mazzola testified that Plaintiff's tooth #31 was removed as a "precautionary" measure before she began chemotherapy. The tooth was decayed, and he and Dr. Nicholson were concerned that it might become infected during the course of treatment. Extracting the tooth was the only way to alleviate that concern because a root canal was not a viable option. Mazzola Dep. at 62. But for the fact that Plaintiff would be undergoing chemotherapy in the near future, it does not appear that there was any urgent need to extract the tooth. Because the tooth was removed solely as a "precautionary" measure, it can be reasonably inferred that, if Dr. Nicholson and Dr. Mazzola had known that invasive dental procedures often trigger ONJ, they

would have adopted a "wait and see" approach, proceeding with the chemotherapy without extracting the tooth.

Moreover, Dr. Nicholson testified that he generally discusses the side effects of medications, "particularly intravenous medicines," with his patients. Nicholson Dep. at 53. It can be inferred that, had he known of the risk of ONJ, he would have discussed this with Plaintiff before giving her Aredia®. Plaintiff unequivocally testified that if she had been told that there was any chance that Aredia® would cause ONJ, she would not have taken it, even if her doctor had recommended it. Pl. Dep. at 98-99, 107 (Ex. 1 to Doc. #47).

NPC argues that Plaintiff's testimony should be disregarded as self-serving and speculative. In *Payne v. Novartis Pharmaceuticals Corporation*, No. 1:12-cv-77 (E.D. Tenn. Sept. 6, 2013), submitted by NPC as supplemental authority, Ex. 1 to Doc. #63, the plaintiff submitted a similar affidavit stating that, had she known of the risk of ONJ, she would not have taken the drug at all. That court rejected her affidavit as "entirely speculative." *Id.* at 18-19 n.9. This Court is not bound by the *Payne* ruling, and respectfully disagrees concerning the speculative nature of the statement. Notably, as soon as Plaintiff herein was diagnosed with ONJ in 2006 and learned that it likely resulted from her use of Aredia®, she stopped taking the drug. Pl. Dep. at 124-25.

NPC argues that Plaintiff's credibility is undercut by the fact that, in 2007, after being diagnosed with ONJ, Plaintiff received one more dose of Zometa®. Dr. Lavelle insists that he discussed the drug with her before giving it to her. Lavelle

Dep. at 33 (Ex. 12 to Doc. #36). Plaintiff testified, however, that she did not remember receiving Zometa® or discussing it with Dr. Lavelle. Pl. Dep. at 93. Although a jury may ultimately find her testimony to be not credible, the Court cannot resolve credibility issues on a motion for summary judgment.

In the Court's view, based on the evidence presented, a reasonable jury could find that the lack of adequate warnings contributed to Plaintiff's use of Aredia® and Zometa®. Her testimony that, had she known of the risk of developing ONJ, she never would have taken Aredia® or Zometa®, combined with Dr. Mazzola's testimony that he refused to extract two of Plaintiff's other teeth after learning that patients who had received bisphosphonate drugs should avoid invasive dental procedures, and Dr. Nicholson's testimony that he would have followed any guidelines issued by NPC, is sufficient to create a genuine issue of material fact concerning proximate causation. Construing all reasonable inferences in Plaintiff's favor, as it must, the Court concludes that a reasonable jury could find that, if NPC had issued timely and adequate warnings, Plaintiff and her doctors, dentists, and oral surgeons would have altered the course of treatment.[4]

NPC also argues that Plaintiff cannot prove that her use of Aredia® and Zometa® caused her to develop ONJ, because she has no admissible expert

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[4] On August 5, 2013, NPC submitted a Notice of Supplemental Authority, Doc. #56, citing *Hill v. Novartis Pharmaceuticals Corp.*, No. 1:06-cv-939 (E.D. Cal. June 26, 2013) (granting a directed verdict in NPC's favor), and *D'Agnese v. Novartis Pharmaceuticals Corp.*, No. CV-12-749 (D. Az. July 2, 2013) (granting NPC's motion for summary judgment). Both decisions were based on the plaintiff's failure to establish proximate cause. Having reviewed those cases, the Court finds them to be factually distinguishable from the case at hand.

witness testimony on this subject. This argument, however, is foreclosed by the Court's decision overruling NPC's motion to exclude the testimony of Dr. Najjar, Plaintiff's retained expert witness, on the topic of specific causation.

For the reasons set forth above, the Court concludes that genuine issues of material fact preclude summary judgment on Plaintiff's "failure to warn" claim.

b. Nonconformance with Manufacturer's Representation

In Count VII of the Amended Complaint, Plaintiff asserts a claim of nonconformance with the manufacturer's representation under Ohio Revised Code § 2307.77. This statute provides as follows:

> A product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

Ohio Revised Code § 2307.77. To recover under this section of the OPLA, a plaintiff must prove:

> 1) that the manufacturer made a representation as to a material fact concerning the character or quality of the manufacturer's product;
> 2) that the product did not conform to that representation;
> 3) that the plaintiff justifiably relied on that representation; and
> 4) that the plaintiff's reliance on the representation was the direct and proximate cause of the plaintiff's injuries.

Gawloski v. Miller Brewing Co., 96 Ohio App.3d 160, 165, 644 N.E.2d 731, 734 (Ohio Ct. App. 1994).

The Court notes that, in connection with her common law claim of breach of express warranty, Plaintiff previously alleged only that NPC represented that

Aredia® was "safe, effective, fit and proper for its intended use." Compl. ¶44. In response, NPC argued that, particularly in cases involving drugs, "asserting that a product is 'safe and effective' is not sufficiently clear to create an express warranty." *In re Meridia Prods. Liability Litigation*, 328 F. Supp.2d 791, 818 (N.D. Ohio 2004).

In her Amended Complaint, in connection with her statutory claim under Ohio Revised Code § 2307.77, Plaintiff now instead alleges that NPC expressly warranted that Aredia® and Zometa® would strengthen bones, and that the side effects were mild and transient. Am. Compl. ¶¶61-62. She further alleges that NPC "represented by denial that its bisphosphonate drugs cause [ONJ]," and that "continued dosing with Aredia and Zometa after two years was effective." Am. Compl. ¶¶63-64. Plaintiff maintains that the products did not conform to these representations. She further alleges that these representations were made to her health care providers who reasonably relied on them and transmitted them to her. Am. Compl. ¶65.

Notably, NPC has not made *any* arguments concerning these new allegations. Rather, NPC maintained that it did not need to modify its motion for summary judgment in response to the Amended Complaint. The moving party always bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of the record which it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). *See also Boretti v. Wiscomb*, 930 F.2d 1150, 1156 (6th Cir.

1991). NPC has wholly failed to satisfy its burden in connection with Plaintiff's statutory claim under Ohio Revised Code § 2307.77. Accordingly, the Court OVERRULES Defendant's motion for summary judgment on Count VII of Plaintiff's Amended Complaint.

c. Punitive and Exemplary Damages

In Count VIII of the Amended Complaint, Plaintiff asserts a claim for punitive and exemplary damages under Ohio Revised Code § 2307.80. Notably, this is not a separate cause of action, and NPC did not move for summary judgment on it. The Court makes no determination concerning whether punitive and exemplary damages might be appropriate if Plaintiff succeeds at trial.

IV. Conclusion

For the reasons stated above, the Court SUSTAINS IN PART and OVERRULES IN PART Defendant NPC's *Daubert* Motion to Exclude Causation Testimony of Plaintiff's Expert Witnesses. Doc. # 34. Although Plaintiff's retained expert, Dr. Najjar, may testify about specific causation, Plaintiff's treating physicians may not.

The Court SUSTAINS IN PART and OVERRULES IN PART Defendant NPC's Motion for Summary Judgment. Doc. #36. Defendant NPC is entitled to summary judgment in its favor on Plaintiff's common claims of strict liability, negligent design defect, negligent failure to warn, breach of express warranty, and breach of implied warranty (Counts I-V of Amended Complaint).

Genuine issues of material fact, however, preclude summary judgment on Plaintiff's claims of failure to warn, and nonconformance with manufacturers' representation, brought under the Ohio Products Liability Act (Counts VI-VII of Amended Complaint). The Court makes no determination at this time concerning the availability of punitive and exemplary damages (Count VIII of Amended Complaint).

Date: September 19, 2013

WALTER H. RICE
UNITED STATES DISTRICT JUDGE