UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Candice Kruszka and Alan Kruszka,

Plaintiffs,

v.

Novartis Pharmaceuticals Corporation,

Defendant.

Civil No. 07-2793 (DWF/JJK)

MEMORANDUM OPINION AND ORDER

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INTRODUCTION

This matter is before the Court on the following motions: (1) Defendant Novartis Pharmaceuticals, Corporation's ("Novartis" or "Defendant") Motion for Summary Judgment (Doc. No. 116) against Plaintiffs Candice Kruszka ("Kruszka" or "Plaintiff") and her husband Alan Kruszka ("Mr. Kruszka") for claims that Kruszka suffered osteonecrosis of the jaw ("ONJ") (or dead jaw bone) as a result of using Novartis's product Aredia®; (2) Novartis's Motion to Exclude Expert Testimony (Causation Testimony) of Plaintiffs' Case-Specific Retained and Non-Retained Expert Witnesses

(Doc. No. 94); and (3) Novartis's Motion to Exclude Expert Testimony of Plaintiffs' Expert Dr. Robert Marx (Doc. No. 61). For the reasons set forth below, the Court grants in part and denies in part the motions.

BACKGROUND

I. General Background

Aredia® ("Aredia") is produced and marketed by Novartis.[1] Aredia is recognized to extend life, reduce skeletal complications and reduce pain for patients with multiple myeloma, a form of blood cancer. (Doc. No. 119 ("Def. Exs."), Ex. 5.) Aredia is part of a class of medications that are known as bisphosphonates, and can be administered intravenously. (*Id.*, Ex. 4.) The primary active ingredient of Aredia is pamidronate disodium ("pamidronate"). (*Id.*) Aredia received FDA approval in 1991 for treating hypercalcemia of malignancy, in 1995 for treating multiple myeloma, and in 1996 for treating bone metastases of breast cancer. (*Id.*, Exs. 8-9.) A generic version of pamidronate was first approved by the FDA in 2001, and others followed. (*Id.*, Ex. 10.)

On June 13, 2000, Kruszka, who was fifty-one years old,[2] presented to her doctor with severe back and hip pain and was unable to sit up or walk. (*Id.*, Exs. 13-15.) During her hospital stay, on June 15, 2000, she was diagnosed with blood cancer in the form of multiple myeloma which resulted in hypercalcemia, a compression fracture in her spine,

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[1] Novartis also makes Zometa® ("Zometa"). Both Aredia and Zometa are bisphosphonates and are used to treat cancer patients, but Kruszka did not receive Zometa.

[2] References to "Plaintiffs" refer to Kruszka and her husband, Mr. Kruszka.

and "lytic" lesions in her skull, spine, and bones. (*Id.*, Exs. 13 & 16 ("Silberstein Dep.") at 55-58.) Her oncologist, Dr. Silberstein, found multiple areas of holes in her bones. (Silberstein Dep. at 57.) During her hospital stay in June 2000, she also suffered an additional fracture in her shoulder due to the brittleness of her bones. (Def. Exs., Ex. 18 ("Kruszka Dep.") at 119.) Multiple myeloma patients' survival rate is approximately six months where no treatment is received. (Def. Exs., Ex. 3.) Kruszka was told she could expect to live six weeks without treatment (Kruszka Dep. at 115-16; Silberstein Dep. at 60-61). On June 15, 2000, Doctor Silberstein immediately prescribed Kruszka Aredia at the Mercy Cancer Center – North Iowa ("Mercy") to protect against bone damage. (Silberstein Dep. at 58-59, 63-65; Def. Exs., Ex. 19.) Kruszka was also treated with chemotherapy consisting of vincristine, adriamycin, and dexamethasone (VAD) at the time of her diagnosis. (Def. Exs., Ex. 20.) Kruszka ultimately received just over fifty doses of pamidronates, with her final dose on February 9, 2005. (*See* Doc. No. 158 ("Odette Aff.") ¶ 3, Ex. 7; Def. Exs., Ex. 41.)

Plaintiff's medical records indicate infusions of Aredia. (Def. Exs., Ex. 41.) Sales reports from Mercy indicate that Mercy purchased branded Aredia until January 18, 2002, after which Mercy only purchased and sold generic pamidronate products. (*Id*., Ex. 12 ("Osland Aff.") ¶¶ 6-9.) Generic drugs dominated the pamidronate market beginning in 2002. (*Id*., Ex. 11 ("Chee Decl.") ¶¶ E, F.)

In January 2001, almost a year after Kruszka started Aredia and VAD therapy, she required a stem cell transplant. (Kruszka Dep. 114; Def. Exs., Ex. 21.) On January 24, 2001, prior to the transplant, Kruszka underwent a dental examination. (Def. Exs.,

Ex. 22.) The oral surgeon, Dr. Keller, noted periodontal disease and determined that Tooth #17 needed to be extracted because it was non-restorable and due to risks of ONJ. (*Id.*, Exs. 22, 23.) On the same day, Dr. Keller extracted Tooth #17. (*Id.*) Four days after the extraction, Kruszka was placed on Melphalan chemotherapy and then a day later underwent the stem cell transplant. (*Id.*, Ex. 26.)

In September 2002, Kruszka presented to her dentist Dr. Nettleton for pain in her lower left jaw and reported that the area had not healed properly following the Tooth #17 extraction. (*Id.*, Ex. 28; Kruszka Dep. at 160-62.) Dr. Nettleton observed exposed bone in the lower left mandible area, and referred Kruszka to an oral and maxillofacial surgeon, Dr. Juhlin. (Def. Exs., Ex. 28.) During her September 19, 2002 visit, Dr. Juhlin did not observe any infection in the area. (Odette Aff. ¶ 3, Ex. 10.) Kruszka reported continued pain to Dr. Nettleton. (*Id.*, Ex. 9.) On October 3, 2002, Dr. Juhlin removed dead bone from the area and placed Kruszka on antibiotics. (Def. Exs., Ex. 29.) Continuing through October and November 2002, Kruszka continued to visit doctors for her pain, and each doctor concluded that she did not show a sign of infection. (Odette Aff. ¶ 3, Exs. 8, 10.)

On December 27, 2002, Dr. Juhlin extracted Kruszka's Tooth #21. (*Id.*, Ex. 10.) On January 7, 2003, at her follow-up visit, Dr. Juhlin recorded no sign of infection. (*Id.*) Kruszka reported continued dental pain in February 2003 at Mayo Clinic ("Mayo"). (*Id*, Ex. 8.)

On March 12, 2003, Kruszka returned to Dr. Nettleton's office, and staff was not able to make any conclusions regarding her condition. (*Id.*, Ex. 9; Kruszka Dep. at 46.)

On March 17, 2003, Kruszka reported pain and bone fragments protruding through her gum to Dr. Juhlin. (Odette Aff. ¶ 3, Ex. 10.) On March 18, 2003, Kruszka was observed at Mayo and was instructed to take on a non-chew diet and to limit mouth opening. (*Id.*, Ex. 8.) That same day, Dr. Juhlin observed exposed bone, no signs of infection, and recommended a surgical exploration and mandibular debridement procedure for her pain. (*Id.*, Ex. 10.)

On April 3, 2003, Kruszka underwent a debridement procedure and extraction of Tooth #19. (Def. Exs., Ex. 30; Odette Aff. ¶ 3, Ex. 10.) At that visit, Dr. Juhlin diagnosed Kruszka with chronic osteomyelitis (infection in the bone). (Def. Exs., Ex. 30; Odette Aff. ¶ 3, Ex. 10.) Dr. Juhlin submitted a specimen of the dead bone for pathological analysis. (Def. Exs., Ex. 30; Odette Aff. ¶ 3, Ex. 10.) The pathologist found inflammation within the bone marrow and "confirm[ed] the presen[ce] of osteomyelitis" in the bone. (Def. Exs., Ex. 32.)[3]

On April 28, 2003, Kruszka returned to Dr. Juhlin with facial swelling and had an abscess in her left mandible drained. (*Id.*, Ex. 33.) Dr. Juhlin then referred Kruszka to an infectious disease specialist, Dr. Terrell, at Mayo to treat her jaw problems. (*Id.*, Ex. 34.) Dr. Terrell diagnosed Kruszka with osteomyelitis and prescribed Kruszka a prolonged (more than six month) course of four different antibiotics after determining that her prior treatments were "suboptimal." (*Id.*, Exs. 36 & 37 ("Terrell Dep.") at 26-27, 31-34.)

[3] The causal connection between osteomyelitis and ONJ and between bisphosphonate-use and ONJ are in dispute here. However, there appears to be a general consensus that there is some association between bisphosphonates and ONJ.

On August 27, 2003, Dr. Juhlin again removed dead bone from the area. (Def. Exs., Ex. 38.) At that time, Kruszka's condition was generally resolved. (Kruszka Dep. at 172-75, 237-39.) In August 2004, however, Kruszka complained of numbness in her jaw, chin, and lip resulting in difficulty swallowing and chewing, a "deformed face," and other issues. (Odette Aff. ¶ 3, Ex. 11; Kruzska Dep. at 53, 72, 171-72, 175-78.) Kruszka alleges the damage to her face and jaw has changed her life dramatically, including her speech, eating, social interactions, and she alleges she had to give up her church choir. (Kruszka Dep. at 53-54, 192-93, 223-24.) Kruszka did not suffer additional bone fractures until May 2008, and as of November 2013, was still alive. (Def. Exs., Ex. 42; *see* Doc. No. 118 at 12 ("she is alive today").)

With respect to Aredia, in May 2004, Dr. Gertz, an oncologist who treated Kruszka, gave her information regarding an association between bisphosphonate use and the development of ONJ; that was the first time she received this type of information on Aredia. (Def. Exs., Ex. 40.)

Novartis first started providing warnings relating to an association between bisphosphonate use and ONJ in its FDA-approved labeling of Aredia and Zometa in September 2003. (*Id*., Exs. 62 & 63.) Novartis revised the label a second time in 2004 to include precautions relating to dental procedures. (*See id.*, Exs. 66 & 67.) Novartis also sent thousands of "Dear Doctor" letters on these issues in September 2004. (*Id*., Ex. 68.)

II. Plaintiffs' Expert Dr. Marx

Dr. Robert Marx, D.D.S. ("Dr. Marx") is a board-certified oral and maxillofacial surgeon at the University of Miami School of Medicine and has practiced in the area for

decades. (Doc. No. 71 ("Def. Marx Exs."), Ex. 1 ("Marx Report") at ¶ 1.) He is involved in research and a number of publications relating to bisphosphonates and ONJ. (*Id.* ¶¶ 5, 10.) He is one of the first medical professionals to have explored a connection between bisphosphonates and ONJ. (*Id.* ¶ 10.) In this case, and a number of other related cases, Dr. Marx seeks to provide (or has provided) his expert opinion with respect to what is called "bisphosphonate-induced osteonecrosis of the jaw" ("BIONJ"). (*Id*. ¶ 14.) Dr. Marx was initially designated by the MDL Steering Committee to address certain topics addressed in his 2008 expert report. In the MDL proceedings, Novartis's motions to exclude Dr. Marx's testimony were denied in part without further analysis. *See In re Aredia & Zometa Prods. Liab. Litig.*, MDL No. 06-1760 (M.D. Tenn. Aug. 13, 2009).

III. Kruszka's Treating Physicians: Dr. Gertz and Dr. Juhlin

Dr. Morie Gertz ("Dr. Gertz") is the oncologist who ultimately took over management of Kruszka's treatment from Dr. Silberstein. (Doc. No. 154 ("Odette Causation Expert Aff.") ¶ 3, Ex. 9 ("Gertz Dep.") at 105.) His area of expertise is in hematology. (*Id.* at 4.) Dr. Gertz has authored three articles on bisphosphonates and, based on his research and experience, his medical opinion is that bisphosphonates cause BRONJ. (*Id*. at 6-9.) In treating patients, Dr. Gertz often discontinues bisphosphonates after a year or two for patients who have a "complete response" to myeloma treatment. (*Id.* at 66-68, 86, 90.) Dr. Gertz also participated in the authoring of the Mayo Clinic revised guidelines for bisphosphonate use in 2006. (Odette Causation Expert Aff. ¶ 3, Ex. 6.) Dr. Gertz testified that he would have changed his treatment of Kruszka had he known the risks associated with bisphosphonates at the time. (Gertz Dep. at 91, 95, 113.)

Dr. Gertz testified that Kruszka's ONJ was bisphosphonate related, but did not diagnose her as having BRONJ at the time of treatment. (*Id.* at 96.)

Dr. Todd Michael Juhlin ("Dr. Juhlin") is an oral maxillofacial surgeon in Iowa. (Odette Causation Expert Aff. ¶ 3, Ex. 8 ("Juhlin Dep.") at 3.) Dr. Juhlin treated Kruszka. (*Id*.) Dr. Juhlin has treated approximately ten patients with ONJ and has also had patients with osteomyelitis. (*Id.* at 23-26.) Dr. Juhlin observed Kruszka with exposed bone in her mouth for approximately eighteen months beginning in 2002 and again at a later date. (*Id.* at 41-42, 51.) Dr. Juhlin diagnosed Kruszka with osteomyelitis and recommended extractions and debridement. (*Id.* at 52-53.) Dr. Juhlin testified that he has changed his treatment of patients since treating Kruszka based on information related to bisphosphonates. (*Id.* at 90, 93, 99.) Dr. Juhlin now believes Kruszka suffered from BRONJ. (*Id.* at 99-100.)

IV. Plaintiffs' Expert Dr. Kraut

Dr. Richard Alan Kraut ("Dr. Kraut") is Plaintiffs' retained witness who has presented an expert report relating to issues of causation. (*See* Doc. No. 102 ("Def. Causation Exs."), Ex. 27 ("Kraut Report").) Dr. Kraut is board-certified in oral and maxillofacial surgery, oral medicine, and dental anesthesia. (*Id.* ¶ A.) Dr. Kraut has worked in these areas for decades. (*Id.*) Dr. Kraut has published a study and a related article on patients taking bisphosphonates. (*Id*.) Dr. Kraut reviewed Kruszka's medical and dental records in giving his expert opinion. (*Id.* ¶ B.) Dr. Kraut states in his report that he performed a "thorough differential diagnosis" in developing his opinion. (*Id.*)

V. Claims

Plaintiffs assert the following claims against Defendant: (1) strict liability; (2) negligence – negligent manufacture; (3) negligence – failure to warn; (4) breach of express warranty; (5) breach of implied warranty;[4] (7) loss of consortium; and (8) punitive damages. (Doc. No. 39, Am. Compl. ¶¶ 18-59.) In its motion, Defendant seeks summary judgment for the following: all liability relating to infusions after January 2002; for Plaintiffs' failure to warn claims; on the grounds that Plaintiffs have no admissible evidence of specific causation; for Plaintiffs' design defect and implied warranty claims; and for punitive damages. Defendant also seeks to exclude the testimony of Dr. Marx relating to six separate issues, and the causation-related testimony of Dr. Gertz, Dr. Juhlin, and Dr. Kraut.

DISCUSSION

I. Motions to Exclude Expert Testimony

A. Legal Standard

Before accepting the testimony of an expert witness, the trial court is charged with a "gatekeeper" function of determining whether an opinion is based upon sound, reliable theory, or whether it constitutes rank speculation. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589-90 (1993) ("*Daubert*"). In *Daubert*, the United States Supreme Court

[4] Plaintiffs had previously asserted claims for Violation of the Consumer Fraud Act (Count VI) and relating to manufacturing (pled as parts of Counts I and II) (Am. Compl. ¶¶ 18-31, 48-51), but have withdrawn those claims. (Def. Exs., Ex. 72.)

imposed an obligation upon trial court judges to ensure that scientific testimony is not only relevant, but also reliable under the Federal Rules of Evidence. *Id*. at 579.

Proposed expert testimony must meet three prerequisites to be admissible under Federal Rule of Evidence 702. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). "First, evidence based on scientific, technical or other specialized knowledge must be useful to the fact-finder in deciding the ultimate issue of fact." *Id.* "[I]t is the responsibility of the trial judge to determine whether a particular expert has sufficient specialized knowledge to assist jurors in deciding the specific issues in the case." *Wheeling Pitts. Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001). Second, the proposed expert must be qualified. *Id.* Third, the proposed evidence must be reliable. *Id.* The proponent of the expert testimony bears the burden to prove its admissibility by a preponderance of the evidence. *Daubert*, 509 U.S. at 592 n.10.

In determining whether the proposed expert testimony is reliable, the Court can consider: (1) whether the theory or technique can be and has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known rate of potential error; and (4) whether the theory has been generally accepted. *Id.* at 593-94. The purpose of these requirements "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

In *Kumho Tire*, the Supreme Court concluded that "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Id.* In other words, a trial court should consider the specific factors identified in *Daubert* where there are reasonable measures of the reliability of expert testimony. *Id.* The objective of that requirement is to ensure the reliability and relevance of expert testimony. *Id.*

The Court's focus should be on whether the testimony is grounded upon scientifically valid reasoning or methodology. *United States v. Dico, Inc.*, 266 F.3d 864, 869 (8th Cir. 2001). "As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination. Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001.)

B. Defendant's Motion to Exclude Expert Testimony of Plaintiffs' Expert Dr. Robert Marx

Defendant moves to exclude discrete aspects of the testimony of Dr. Marx, Plaintiffs' retained oral surgery expert witness. Defendant moves to exclude Dr. Marx's testimony on the basis of Federal Rules of Evidence 401-403, 702, and *Daubert*. Specifically, Defendant seeks to preclude Dr. Marx from: (1) presenting opinions regarding dose and duration; (2) presenting opinions about certain dental evaluation and treatment measures that he claims prevent BIONJ; (3) speculating that certain patients in

the Zometa and Aredia clinical trials had ONJ caused by bisphosphonate therapy; (4) presenting general causation opinions based on adverse event reports that he has not reviewed; (5) testifying about the biological mechanism by which bisphosphonates allegedly caused ONJ; and (6) accusing Novartis of bad faith conduct.[5]

i. Pre-Dental Screening, Clinical Trial Patients Having BRONJ, and Causation

Plaintiffs point to the law of the case doctrine in support of their claim that the Court need not revisit the issue of the exclusion of Dr. Marx's testimony. Generally, with respect to the doctrine of the law of the case, "orders issued by a federal transferee court remain binding when the case is remanded to the transferor court. The doctrine of the law of the case provides that, when a court decides a rule of law, its decision should govern the same issues in subsequent stages in the same case." *Lemmon v. Wyeth, LLC*, Civ. No. 04-1302, 2012 WL 2848161, at *5 (E.D. Mo. July 11, 2012) (citing *Winter v. Novartis Pharms. Corp.*, Civ. No. 06-4049, 2011 WL 5008008, at *2 (W.D. Mo. Oct. 20, 2011)) (internal quotations omitted).

Defendant argues that the law of the case doctrine is more limited than Plaintiffs assert. The Court agrees with Defendant that the applicability of the law of the case doctrine is not automatic and is "discretionary, allowing a court to depart from the law of the case if cogent or compelling reasons to do so are shown." *Id*. Moreover, the Court is required to exercise its "gatekeeper" function under *Daubert* to ensure testimony is

[5] Plaintiffs have agreed not to present testimony relating to: (1) state of mind, intent, or motives of Novartis or the FDA; and (2) criticisms of the Aredia and Zometa clinical trials. (Def. Marx Exs., Ex. 11.)

reliable and relevant. *See Daubert*, 509 U.S. at 589-90. However, it is also the case that "principles of efficiency and comity make the Court hesitant to disturb the MDL court's ruling as doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings." *Winter*, 2011 WL 5008008, at *2 (internal citations and quotations omitted).

Here, at least with respect to issues (2), (3), and (4) above (pre-dental screening, clinical trial patients having BRONJ, and causation), the Court agrees with Plaintiffs that these issues have already been thoroughly examined and decided by the MDL court. The MDL court specifically considered these very issues and held that "Dr. Marx's testimony is clearly more than unsupported speculation." (Doc. No. 141 ("Odette Marx Exs."), Ex. 2 at 3.) The Court has reviewed the pleadings and supporting documents regarding Dr. Marx's testimony on these issues and agrees with the MDL court that Dr. Marx's testimony is reliable and relevant. Therefore, with respect to Dr. Marx's testimony relating to issues (2), (3), and (4) above, Defendant's motion is denied.[6]

ii. Dose and Duration

Defendant argues that testimony relating to dose and duration is beyond Dr. Marx's expertise and is not the product of a reliable scientific methodology. Specifically, Defendant argues that because Dr. Marx is not an oncologist or other

[6] The Court reserves the right to address issues relating to reports that Dr. Marx has not reviewed should they arise during trial, including not only Rule 703 issues, but foundation issues pursuant to Rule 104. *See* Fed. R. Evid. 104, 703.

medical doctor and does not prescribe Aredia and Zometa, he cannot testify to issues of appropriate dosage and duration.

First, the Court concludes that Dr. Marx is qualified to be an expert under Rule 702 with respect to bisphosphonates and ONJ. Dr. Marx is a certified oral maxillofacial surgeon with decades of experience in this area. (*See* Marx Report ¶ 1.) He is heavily involved in research relating to bisphosphonates and ONJ and has issued a number of publications on these topics. (*See generally id.*) He is one of the first physicians to have explored a connection between bisphosphonates and ONJ. (*Id*. ¶ 10.)

Second, given his expertise in this area, the Court concludes that Dr. Marx is also qualified to opine on the sub-issue of dose and duration for bisphosphonates. However, his qualification on this subject is limited to testimony based on his experience and research related to dose and duration. For example, Dr. Marx may testify to opinions he has derived from his own observations and studies. (Marx Report at ¶ 48 (relating to data collected for 119 patients and indicating increased severity of cases with increased dosage).) Such evidence provides factual support for an opinion relating to dosage and duration. To the extent that the basis of his knowledge for conducting any such studies stems from learned treatises or other acceptable studies, Dr. Marx may also offer testimony regarding those studies. Of course, the admissibility of that testimony will be subject to the proper foundation being laid and to Rule 703, and does not automatically render any such study admissible without proper examination under the Federal Rules of Evidence.

However, Dr. Marx cannot reliability testify to the results or efficacy of differing dose and duration. For example, Dr. Marx testifies that he cannot predict whether a dosing scheduling change would alter the risk of ONJ (Marx. Dep. at 306, 338). He also cannot opine regarding whether dosage changes impact the efficacy of the drugs at issue. Neither is within his area of expertise and he has not shown the application of any scientifically valid reasoning or methodology with respect to such opinions. Similarly, Dr. Marx is not qualified to give the opinion that a different dose would have prevented or lessened the risk of Kruszka's jaw disease, or that an oncologist could or should have prescribed her a different dose or duration, as he has not shown any scientific evidence to support such an opinion. (Def. Marx Exs., Ex. 18 (trial transcript in *Guenther v Novartis Pharms. Corp.*, Civ. No. 08-456-31 (M.D. Fla. Sept. 13, 2013) (excluding Dr. Marx's testimony opining that a different dose would have prevented or lessened the plaintiff's risk of jaw disease).) Any opinion on these matters would not be based on facts or studies known to Dr. Marx and as such would require extrapolation by Dr. Marx, thereby creating "too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *see, e.g.*, *Conklin v. Novartis Pharms. Corp.*, Civ. No. 11-178, 2012 WL 4127295, at *9-10 (E.D. Tex. Sept. 18, 2012).

Therefore, Defendant's *Daubert* motion is granted in part and denied in part. Dr. Marx may opine on dose and duration to the extent that any such testimony is grounded in specific studies or research and meets the requirements of the Federal Rules of Evidence, but may not generally opine on the results or efficacy of altered dose and duration.

iii. Biological Mechanisms Through Which Bisphosphonates Cause ONJ

Defendant asserts that Dr. Marx lacks both particular expertise and reliable scientific methodology upon which to base any conclusions about how Aredia affects human cancer patients' jaw bones. Defendant asserts that Dr. Marx is not a "bone biologist, endocrinologist, pharmacologist, or an expert on how bisphosphonate drugs affect the bone," and that he relied on animal studies rather than human ones in arriving at his opinions. The Court concludes that Dr. Marx is qualified to testify about the biological mechanisms by which bisphosphonates cause ONJ. Dr. Marx has extensive background in treating and studying patients with ONJ and, as a result, he is competent to testify as an expert about this topic.

Defendant also asserts that Dr. Marx's reliance on an animal-based study is misplaced and that he fails to address studies that indicate the opposite of his opinion. These issues go to the weight of Dr. Marx's testimony, not its admissibility. As such, Defendant may test the credibility of Dr. Marx's opinions—and methodology—on cross examination, rebut the testimony with its own witnesses, and submit its own contrary expert evidence; the jury can thus determine the credibility of, and weight to be given to, his testimony. *See, e.g., Rockwood Retaining Walls, Inc. v. Patterson, Thuente, Skaar & Christensen, P.A.*, Civ. No. 09–2493, 2011 WL 2845529, at *5 (D. Minn. July 18, 2011). But, here, the Court resolves any doubts regarding the overall value of Dr. Marx's testimony in favor of its admissibility. *See Clark by Clark v. Hendrick*, 150 F.3d 912, 915 (8th Cir. 1998) (noting that "doubts regarding whether an expert's testimony will be

useful should generally be resolved in favor of admissibility"). Of course, the admissibility of Dr. Marx's testimony will be subject to the proper foundation being laid. Therefore, Defendant's *Daubert* motion with respect to testimony on biological mechanisms through which bisphosphonates cause ONJ is denied.

iv. Novartis and Bad Faith Conduct

Defendant argues that to the extent Dr. Marx's testimony addresses his personal opinions regarding whether Novartis's actions were "bad corporate conduct," that testimony should be excluded under *Daubert*, Federal Rules of Evidence 401, 402, 403, and 702. The Court believes that this issue has been addressed by agreement of the parties (Def. Marx Exs., Ex. 11)—that is, both the Court and the parties agree that Dr. Marx cannot testify about the state of mind, intent, or motives of Novartis. *See, e.g.*, *Winter v. Novartis Pharms. Corp.*, 2012 WL 827305, at *8-9. The Court and the parties are further in agreement that Dr. Marx can testify as a fact witness based on his personal experience working with Novartis. *See id.*; *see also Hogan v. Novartis Pharms. Corp.*, 2013 WL 1533467, at *4 ("[T]he Court will also allow Dr. Marx to testify as a fact witness to describe, briefly, the content of his interactions with defendant to show when defendant first knew about ONJ."). To the extent further issues arise with respect to Dr. Marx's testimony on alleged "bad faith" conduct, the Court reserves the right to address those issues at trial.

C. Motion to Exclude Expert Testimony (Causation Testimony) of Plaintiffs' Case-Specific Retained and Non-Retained Expert Witnesses

Defendant moves to exclude specific causation testimony by Kruszka's doctors, Dr. Gertz and Dr. Juhlin, as well as by Plaintiffs' retained expert Dr. Kraut, on the basis of Federal Rule of Evidence 702 and *Daubert*.

With respect to Drs. Gertz and Juhlin, in their supplemental Rule 26(a)(2)(B) disclosures, Plaintiffs included the following disclosure: (1) "[Dr. Gertz] is expected to testify that Aredia contributed to Mrs. Kruszka's ONJ"; and (2) "[Dr. Juhlin] is expected to testify that Mrs. Kruszka had BRONJ caused by her use of Aredia." (Def. Causation Exs., Ex. 1 ¶¶ 1, 3.) Specifically, Defendant seeks to preclude Dr. Gertz and Dr. Juhlin from offering specific causation opinions on the basis that they do not have expertise in bisphosphonates or ONJ and have testified they have no specific causation opinion.

Defendant seeks to preclude Dr. Kraut from testifying on the basis that his opinion is scientifically unreliable and contains omissions as to Kruszka's medical history.

i. Dr. Gertz and Dr. Juhlin

It is not disputed that a treating physician can give opinion testimony relating to information gained through a patient's care, diagnosis, and treatment: that is, a treating physician can testify about information related to and learned through treating the patient and that is based on personal knowledge. *See, e.g.*, *Crabbs v. Wal-Mart Stores, Inc.*, Civ. No. 09-00519, 2011 WL 499141, at *2-3 (S.D. Iowa Feb. 4, 2011). However, "[a] treating physician's expert opinion on causation is subject to the same standards of scientific reliability that govern the expert opinions of physicians hired solely for

purposes of litigation." *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1207 (8th Cir. 2000); *Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008) (internal citations omitted).

a. Dr. Gertz

Defendant argues that Dr. Gertz should be precluded from presenting testimony on specific causation for the following reasons: (1) there is no evidence that he is qualified to opine on the cause of Kruszka's ONJ where he admits he is not an expert; and (2) he failed to do a differential diagnosis as is required to present expert testimony on causation.

Dr. Gertz was Kruszka's second treating oncologist. By his own testimony, Dr. Gertz did not treat Kruszka's jaw conditions, and he does not have specific training or expertise in jaw conditions. Dr. Gertz, however, has authored three articles on bisphosphonates, two of which relate to the association between bisphosphonates and ONJ. He also has significant experience treating patients with myeloma and prescribing bisphosphonates. Thus, Dr. Gertz may have sufficient "knowledge, skill, experience, training or education" with respect to bisphosphonates to meet the requirements for admissibility under Rule 702.

However, here, the Court need not determine whether Dr. Gertz has sufficient expertise because Plaintiffs fail to establish sufficient reliability. Dr. Gertz's testimony as to specific causation is not sufficiently grounded in the methods and procedures of science to be admissible under *Daubert* and Rule 702. *See Daubert*, 509 U.S. 589-90. In fact, Plaintiffs fail to present any testimony that addresses the application of any scientific

methodology with respect to Dr. Gertz's opinion that Kruszka's condition was caused by Aredia. Plaintiffs present no evidence that Dr. Gertz performed a differential diagnosis regarding the cause of Kruszka's jaw condition, and there is also no testimony that he reviewed or ruled out any other causes. (Gertz Dep. at 36-38.) Instead, Dr. Gertz makes clear that his understanding as it relates to bisphosphonates is based on his experience alone: "I've not done research in bisphosphonates. I have not been the principal investigator of any clinical trials in bisphosphonates. I see patients with multiple myeloma and I prescribe bisphosphonates, so I have experience," (*id.* at 30) and, "[my opinion that bisphosphonates can cause ONJ, is] based on, one my own personal experience . . . [a]nd subsequently published literature" (*id.* at 9-10).

When asked specifically for the basis of his opinion that there was a causal link between bisphosphonates and Kruszka's ONJ, Dr. Gertz stated that basis of his opinion that Aredia was "contributory" was "personal experience and my understanding of the literature surrounding bisphosphonate use and osteonecrosis of the jaw." (*Id.* at 36.) In fact, Dr. Gertz could not even opine on whether Kruszka's jaw problems were ONJ (*id.* at 38), making an opinion on causation for Kruszka's conditions unreliable.

Plaintiffs have thus provided no evidence to suggest that Dr. Gertz can opine regarding any connection between bisphosphonates and Kruszka's ONJ. This, however, does not preclude Dr. Gertz from testifying to opinions formed during the course of and relating to Kruszka's treatment and diagnoses.

b. Dr. Juhlin

Defendant argues that Dr. Juhlin should be precluded from presenting testimony on specific causation for the following reasons: (1) he did not diagnose Kruszka with BRONJ while treating her and instead repeatedly diagnosed her with osteomyelitis; (2) he failed to conduct a differential diagnosis as is required to present expert testimony on causation; (3) his opinion on causation is not reliable based on his lack of differential diagnosis.

Dr. Juhlin was Kruszka's oral maxillofacial surgeon. Like Dr. Gertz, Dr. Juhlin also fails to show that he ever independently determined the cause of Kruszka's ONJ. Dr. Juhlin has extensive experience in his field of oral surgery dating back to the mid-nineties, and has treated approximately seven to ten patients with ONJ. However, Dr. Juhlin never diagnosed Kruszka with ONJ, did not know she was using Aredia while he was treating her, and only reached his opinion that Kruszka likely had ONJ as of the date of his deposition in this matter. (Juhlin Dep. at 110, 116-17.) Plaintiffs seek to base Dr. Juhlin's specific causation testimony on views he developed long after he treated Kruszka; this does not form the basis of an expert opinion based on "the exacting standards of reliability" required by *Daubert* and Rule 702. *See Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000).

As with Dr. Gertz, Plaintiffs have thus provided no evidence to suggest that Dr. Juhlin can opine regarding a connection between bisphosphonates and Kruszka's ONJ—he is therefore precluded from presenting specific causation testimony. This, however, does not preclude Dr. Juhlin from testifying to opinions formed during the course of and

relating to Kruszka's treatment, and also does not preclude him from speaking to his office procedures with respect to bisphosphonates.

ii. Dr. Kraut

Defendant seeks to exclude Dr. Kraut's specific causation testimony under *Daubert* and Rule 702 on the grounds that his differential diagnosis is not valid or reliable. Defendant argues that his methodology is not reliable because: (1) he always concludes that if a patient takes bisphosphonates, then bisphosphonates caused the ONJ; and (2) he failed to rule out osteomyelitis by reliable methodology.

Specifically, Defendant claims that Dr. Kraut: ignored signs and symptoms of osteomyelitis, though they were present; ignored pathology demonstrating osteomyelitis when he failed to review Kruszka's biopsy and associated pathology slide, relying instead on an article by Dr. Marx; and failed to rule in or out other possible causes of Kruszka's problems, even though she had risk factors for them (for example, peridontial disease, which involves a number of similar symptoms to those suffered by Kruszka). Plaintiffs dispute that Dr. Kraut's methodology is improper and point to a number of reasons his diagnosis is appropriate.

Having reviewed the pleadings and evidence submitted, the Court finds that Defendant's arguments do not render Dr. Kraut's testimony inadmissible under Rule 702 and *Daubert*. As stated in *In re Aredia & Zometa Prods. Liab. Litig. (Eberhart)*, Civ. No. 08-913, 2010 WL 5072008, at *2 (M.D. Tenn. Dec. 7, 2010):

> Dr. Kraut's testimony is more than unsupported speculation. Reliable Causation testimony need not rule out every possible alternative cause. *Kudabeck v. The Kroger Co.*, 338 F.3d 856, 861 (8th Cir. 2003). The fact

> that several possible causes might remain "uneliminated" only goes to the accuracy of the conclusion, not to the soundness of the methodology.

This Court agrees and concludes that Dr. Kraut may provide his expert opinion on specific causation. *See, e.g.*, *Hill v. Novartis Pharms. Corp.*, Civ. No. 06-3939, 2012 WL 5451800, at *2 (E.D. Cal. Nov. 7, 2012) (admitting Dr. Kraut's testimony); *Davids v. Novartis Pharms. Corp.*, 857 F. Supp. 2d 267, 278-279 (E.D.N.Y. 2012) (same); *Eberhart*, 2010 WL 5072008, at *2 (admitting Dr. Kraut's testimony and referencing the court's identical decisions relating to Dr. Kraut in *Baldwin/Winter*, Civ. No. 06-496; *Kyle/Mahaney*, Civ. No. 06-495; and *McDaniel*, Civ. No. 08-908); *see also McKay v. Novartis Pharms. Corp.*, EP-06-CA-63-FM (W.D. Tex. Feb. 10, 2012) (admitting Dr. Kraut's testimony).

Defendant's attempt to differentiate Dr. Kraut's testimony here from his testimony in other cases on the basis of specific facts of this case with respect to Kruszka fails. As with Dr. Marx, at their core, Defendant's challenges appear to go to the weight of Dr. Kraut's testimony, not its admissibility. *See Bonner*, 259 F.3d at 929-30 ("[T]he factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility . . ."). As such, Defendant may test the credibility of Dr. Kraut's opinions—and methodology—on cross examination, rebut the testimony with its own witnesses, and submit its own contrary expert evidence; the jury can determine the credibility of, and weight to be given to, Dr. Kraut's testimony. *See, e.g.*, *Rockwood Retaining Walls*, 2011 WL 2845529, at *5.

Here, the Court resolves any doubts regarding the overall value of Dr. Kraut's testimony in favor of its admissibility. *See Clark by Clark*, 150 F.3d at 915. Of course, the admissibility of Dr. Kraut's testimony will be subject to the proper foundation being laid. Therefore, Defendant's *Daubert* motion with respect to Dr. Kraut is denied.

II. Defendant's Motion for Summary Judgment

A. Legal Standard

Summary judgment is proper if there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The Court must view the evidence and the inferences that may be reasonably drawn from the evidence in the light most favorable to the nonmoving party. *Enter. Bank v. Magna Bank of Mo.*, 92 F.3d 743, 747 (8th Cir. 1996). However, as the Supreme Court has stated, "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy, and inexpensive determination of every action.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24, 327 (1986) (quoting Fed. R. Civ. P. 1).

The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. *Enter. Bank*, 92 F.3d at 747. The nonmoving party must demonstrate the existence of specific facts in the record that create a genuine issue for trial. *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995). A party opposing a properly supported motion for summary judgment "may not rest upon the mere allegations or denials of his pleading, but must set

forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986).

B. Analysis

i. Generic Pharmaceuticals

In the Eighth Circuit, pharmaceutical manufacturers of branded products are not liable for injuries caused by generic products manufactured by others. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612-614 (8th Cir. 2009), *reaffirmed in pertinent part and vacated on other grounds*, 658 F.3d 867 (8th Cir. 2011); *see also Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1092-93 (8th Cir. 2013). This means a plaintiff must prove that the defendant supplied the injury-causing product at issue. *See Mensing*, 588 F.3d at 612-614.[7]

[7] While this is currently the law in the Eighth Circuit, the Court recognizes that the state of law on this issue has been recently called into question, though not directly addressed. In her concurring opinion in *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 747-48 (8th Cir. 2013), Justice Murphy notes that the "foundation of [the] analysis" relied on in *Mensing* and *Bell* (above) was "severely eroded" by the Supreme Court decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). She argues that *PLIVA* and *Bartlett*:

> stripped any discretionary authority from the generic manufacturers to ensure the safety of the products or the adequacy of the labels, instead placing the burden entirely on the brand manufacturers. The privileged position accorded to the brand manufacturers may alter their state law relationship to the generic drugs whose composition and labeling they control, since at this point such a manufacturer is the party that actually controls the manufacturing and labeling of the product in question. With the brand manufacturers solely responsible for the content and updating of a generic's labels, it can no longer be credibly argued that communications regarding the risks of [a brand manufacturer's] product are not also directed at the consumers of generic bioequivalents.

Fullington, 720 F.3d at 748 (internal citations and quotations omitted).

Defendant argues that in this case, "the testimony of the pharmacy manager at [the hospital] as well as the sales records of the sole supplier in the relevant time shows that Plaintiff could not have received Aredia after January 2002" (Doc. No. 118 at 18), and that as a result, summary judgment should be granted as to any liability for infusions Kruszka received after January 2002. Specifically, Defendant presents the affidavit of Mercy's Director of Pharmacy who supervised purchasing, distribution, and inventory during the time period at issue. (*See generally* Osland Aff.) The affidavit states that Mercy stopped purchasing Aredia and only purchased generic pamidronates beginning in January 2002. (*Id*. ¶ 6-9.) Defendant also provides evidence that generics began to dominate the market starting in 2002 when Areida's share fell from 98% to 35%, and thereafter fell to 7% in 2003, 2% in 2004, and 1% in 2005 and 2006. (Chee Aff. ¶¶ E-F.)

Plaintiffs, however, argue that Defendant can be held liable for injuries caused by pamidronate infusions after 2002 based on the following: the authenticity of Defendant's affidavit cannot be confirmed; Kruszka's medical records indicate Aredia was prescribed; and Aredia has an eleven year half-life and therefore remained in Kruszka's bones after her last dose.

The Court concludes that Novartis has presented sufficient evidence to establish that no genuine issue of material fact exists regarding the drug supplies used for Kruszka's pamidronate infusions. Novartis includes evidence of the supplier's records showing that Kruszka's pharmacy sold generic pamidronate products beginning in February 2002, notwithstanding Plaintiffs' unavailing objections as to the records'

authenticity.[8] Novartis also includes evidence that generic pamidronate had taken predominant market share beginning in 2002. (*See* Chee Aff. at ¶¶ E-F.)

However, the Court also concludes that there is a genuine issue of material fact as to the half-life of Aredia and its impact on Kruszka and on the body. Plaintiffs may present evidence of liability post-2002 to the extent they establish the existence of a half-life for Aredia and some effect as a result of Aredia's half-life.

Thus, the Court grants summary judgment in part as to liability for injuries post-January 2002 to the extent the injury is tied to generic pamidronates, but denies summary judgment to the extent that Plaintiffs' claims relate to injuries caused by Aredia that remained in Kruszka's system as a result of Aredia's half-life.

ii. Failure to Warn

For a failure to warn claim, a plaintiff must show that: "(1) the defendant had a duty to warn; (2) the defendant breached that duty by providing an inadequate warning (or no warning at all); and (3) the defendant's inadequate (or nonexistent) warning caused the Plaintiffs' damages." *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1155 (D. Minn. 2011) (citing *Balder v. Haley*, 399 N.W.2d 77, 81 (Minn. 1987)). Under Minnesota law, Plaintiffs' failure to warn claims based on strict liability and based on negligence merge into a single cause of action. *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 623 (Minn. 1984); *see also Piotrowski v. Southworth Prods. Corp.*, 15 F.3d 748, 751

[8] Defendant will have to lay proper foundation as to this testimony at trial.

(8th Cir. 1994); *Huber v. Niagara Mach. & Tool Works*, 430 N.W.2d 465, 468 n.1 (Minn. 1988) (liability for failure to warn in Minnesota is based on principles of negligence).

A manufacturer has a "duty to exercise ordinary and reasonable care not to expose the potential consumer to an unreasonable risk of harm from the use of its products." *O'Hare v. Merck & Co.*, 381 F.2d 286, 290-31 (8th Cir. 1967). The duty relates only to the time the manufacturer made and sold the product. *Block v. Toyota Motor Corp.*, CIV. 10-2802, 2014 WL 1048500, at *18 (D. Minn. Mar. 18, 2014) (citations omitted). A defendant must have had "reason to know of the dangers of using the product." *Tuttle v. Lorillard Tobacco Co.*, 377 F.3d 917, 924 (8th Cir. 2004). Whether a duty to warn exists is a question of law for the Court to decide. *In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161, 1166 (8th Cir. 2012) (citing *Balder v. Haley*, 399 N.W.2d 77, 81 (Minn. 1987)). Under the learned-intermediary doctrine, a manufacturer of prescription drugs has the duty to warn the prescribing physician (rather than the patient) about the dangers associated with a product. *In re Levaquin*, 700 F.3d at 1166 (citations omitted).

If a legal duty to warn is found, the factual issue of the adequacy of the warning, breach of the duty, and causation are considered by the fact finder. *Balder*, 399 N.W.2d at 81. There must be a "direct causal nexus" between the allegedly defective warning and the injury sustained. *Tuttle*, 377 F.3d at 924. That is, in this case, Plaintiffs must show that if Defendant had issued a proper warning, Ms. Kruszka would not have taken Aredia as she did and would not have developed her jaw condition as a result.

Defendant argues that during the period of time Ms. Kruszka took Aredia (June 2000 to January 2002), Plaintiffs cannot show that Defendant knew or reasonably should

have known of the risk of ONJ because Defendant did not receive its first reports of ONJ until December 2002, and Ms. Kruszka's tooth extraction occurred in January 2001. Defendant also argues that the first case reports on bisphosphonates and ONJ were not published until 2003, at which time Novartis changed its labels. Plaintiffs, however, assert that disputed facts exist regarding whether Defendant could have known and warned about the risk of ONJ in individuals taking Aredia because a number of doctors and certain clinical trials indicated a correlation between bisphosphonates and ONJ.

It is not disputed that, generally, a pharmaceuticals manufacturer has a duty to warn of known dangers associated with their product (or dangers of which they should have known). *See Hill v. Searle Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989); *see also Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn. 1977). Thus, the Court finds that Novartis had a duty to warn (prescribing physicians) of any known dangers associated with Aredia (or dangers of which they should have known). *See In re Levaquin*, 700 F.3d at 1166 (whether there is a duty to warn is a question of law for the court).

When Defendant knew certain information, and whether Defendant's warning, or lack thereof, was sufficient, are all properly put to a jury for resolution. *See In re Levaquin*, 700 F.3d at 1166; *see also Balder*, 399 N.W.2d at 81. Here, viewing the evidence in the light most favorable to Plaintiffs, Plaintiffs have presented evidence that creates a genuine issue of material fact about what Novartis knew about the risks of bisphosphonates, when it knew or should have known of those risks, and whether it adequately conveyed those risks to physicians. *See, e.g.*, *Earp v. Novartis Pharms. Corp.*,

Civ. No. 11-680, 2013 WL 4854488, at *5 (E.D.N.C. Sept. 11, 2013). Plaintiffs present a 1981 study involving rats that shows a connection between bisphosphonates and ONJ. (Doc. No. 30 ("Germany Decl."), Exs. 3-4.) Plaintiffs also present evidence of six cases of ONJ which were allegedly reported to Novartis during Aredia's clinical trials, as well as evidence that doctors presented information regarding a possible connection between bisphosphonates and ONJ to Novartis. (*Id*., Exs. 5A, 10); *see, e.g.*, *Bowles v. Novartis Pharms. Corp.*, Civ. No. 12-145, 2013 WL 5297257, at *9 (S.D. Ohio Sept. 19, 2013). Plaintiffs also present evidence that Novartis employed a strategy with its label changes that indicates they knew of bisphosphonate/ONJ issues. (*See* Odette Aff. ¶ 3, Exs. 14-16.)

Moreover, in the first wave of the Aredia/Zometa® multi-district litigation, the MDL Court determined that genuine issues of material fact precluded summary judgment on the issues of general causation and warning adequacy. *In re Aredia and Zometa Prods. Liability Litigation*, No. 3:06–md–1760, Doc. Nos. 2764, 2767 (M.D. Tenn. Aug. 13 2009). Here, based on the record before the Court, the Court concludes that there is a genuine issue of material fact as to what Novartis knew or should have known during the time periods in question.

Furthermore, viewing the evidence in the light most favorable to Plaintiffs, Plaintiffs have presented evidence that creates a genuine issue of material fact as to whether Kruszka's treatment would have been different if Novartis had provided adequate warning. Plaintiffs present evidence that: (1) Dr. Silberstein may have cut the duration of bisphosphonate treatments as a result of knowing about ONJ risks; (2) he may

have altered the dosage; (3) he would have done a general mouth exam and intake questioning focusing on ONJ; and (4) he would have collaborated more with dentists and oral surgeons. (*See, e.g.*, Silberstein Dep. at 129-31, 136-37.) Dr. Silberstein also states that withholding or stopping bisphosphonates at an earlier time are a possibility where tooth problems are present. (*Id.*) Plaintiffs also present evidence that Kruszka's oral surgeon, Dr. Juhlin, now specifically asks about bisphosphonates when presented with cancer patients due to concerns about ONJ (including questions about whether the bisphosphonates are administered orally or by IV, and about duration of the treatment), and also that he performs fewer surgical procedures on such patients as a result. (Juhlin Dep. at 90-94.) Dr. Juhlin also testified that he probably would have simply observed Kruszka rather than providing surgical care immediately. (*Id*. at 94.) If at least one treating physician, not necessarily the original prescriber of the drug, would have behaved differently, this is sufficient to survive summary judgment. *See, e.g., In re Aredia & Zometa Prods. Liab. Litig.*, Civ. No. 06-550, 2009 WL 2497692, at *2 (M.D. Tenn. Aug. 13, 2009). Here, Plaintiffs point to a number of different treatment possibilities and thus can survive summary judgment.

Defendant does not offer sufficiently compelling evidence that Kruszka's doctors would have taken the exact same course of action with full warnings on ONJ and bisphosphonates. Instead, Defendant argues that Kruszka was so sick she would have taken Aredia in the same manner she did, even with warnings. Kruszka's case, however, differs from cases where Defendant could establish that there was no genuine issue of material fact. For example, in *Luttrell*, doctors continued prescribing Aredia after the

plaintiff was diagnosed with the express determination that the benefits outweighed the risks, and also doctors agreed to restart Aredia treatments after the filing of the lawsuit at issue. *Luttrell*, 894 F. Supp. 2d 1324, 1344 (2012); *see also D'Agnese*, 952 F. Supp. 2d 880, 892-93 (2013) (the doctor prescribed ongoing Zometa treatment in the same dose and frequency years after the plaintiff developed ONJ and the plaintiff continued to take Zometa after being explicitly warned of the risk of ONJ). Here, there is no such determinative evidence that would undermine any genuine issue of material fact.

Thus, Plaintiffs have presented sufficient evidence on duty, breach, and causation to survive summary judgment on the failure to warn claim, and summary judgment is denied.[9]

iii. Specific Causation

Specific causation as to whether Aredia actually caused Kruszka's jaw condition must be proven as an essential element, and must be proven by expert evidence when it is outside the realm of common knowledge. *See Gross v. Victoria Station Farms, Inc.*, 578 N.W.2d 757, 762 (Minn. 1998). Here, the causal link between Aredia and Kruszka's jaw conditions is clearly outside the realm of common knowledge. Because the Court is allowing the expert testimony of Plaintiffs' expert, Dr. Kraut, on issues of specific causation, this requirement has been met and a question of fact remains for the jury.

[9] The Court notes that because under Minnesota law, Plaintiffs' failure to warn claims based on strict liability and negligence merge into a single cause of action, "the plaintiff may submit the case to the jury on only one theory. The plaintiff can plead and prove at trial either or both theories, but by the time the parties rest, the plaintiff must announce whether the case will be submitted to the jury on negligence or strict liability." *Hauenstein v. Loctite Corp.*, 347 N.W.2d 272, 275 (Minn. 1984).

iv. Design Defect and Implied Warranty Claims Fail

a. Breach of Implied Warranty

Plaintiffs allege that Defendant breached the implied warranty of merchantability as Aredia was neither safe for its intended use, nor of merchantable quality because it had dangerous propensities when put to its intended use and could cause severe injuries to the user.

Under Minnesota law, "[s]trict liability has effectively preempted implied warranty claims where personal injury is involved." *Kapps*, 813 F. Supp. 2d at 1162 (citations omitted); *see also In re Levaquin*, 752 F. Supp. 2d at 1079 (citations omitted). Thus, here, Plaintiffs' claims for breach of implied warranty is subsumed by their strict liability claims and warrants dismissal. The Court disagrees with Plaintiffs that this issue should be reserved for the jury charge conference. The implied warranty claim cannot stand as a matter of law and must be dismissed; Defendant's motion for summary judgment as to Plaintiffs' breach of implied warranty claim is granted.

b. Negligent Design Defect

"To survive summary judgment for a design defect claim, Plaintiff must demonstrate that a genuine issue of material fact exists with regard to whether: (1) the defendant's product was in a defective condition unreasonably dangerous for its intended use, (2) the defect existed when the product left the defendant's control, and (3) the defect was the proximate cause of the injury sustained." *Bilotta*, 346 N.W.2d at 623 n.3 (citing *Lee v. Crookston Coca-Cola Bottling Co.*, 188 N.W.2d 426, 432 (Minn. 1971));

Keller v. CNH Am., LLC, Civ. No. 07-1648, 2009 WL 1766695, at *4 (D. Minn. June 22, 2009).

To determine whether a particular product is unreasonably dangerous, the Court applies the "reasonable care balancing test." *Bilotta,* 346 N.W.2d at 621-23. This test focuses on whether the manufacturer has exercised "that degree of care in [the] plan or design so as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to the danger when the product is used in the manner for which the product was intended, as well as unintended yet reasonably foreseeable use." *Ehlers v. Siemens Med. Solutions, USA, Inc.*, 251 F.R.D. 378, 383-84 (D. Minn. 2008) (citing *Bilotta*, 346 N.W.2d at 621). A relevant factor in this balancing test is "evidence of the existence of a feasible, alternative safer design," but it is not an element of a design defect case. *Kallio v. Ford Motor Co.*, 407 N.W.2d 92, 96 (Minn.1987). Thus, "[t]o determine whether there is enough evidence to submit the claim to a jury, the court must balance the likelihood of harm, and the gravity of harm if it happens, against the burden of the precaution which would be effective to avoid the harm." *Young v. Pollock Eng'g Grp., Inc.*, 428 F.3d 786, 788-89 (8th Cir. 2005) (internal citations and quotations omitted).

Plaintiffs assert that part of the failure of design is Defendant's failure to test for ONJ in its trial subjects, including looking in the mouth of subjects. They further argue that it was foreseeable that Defendant should have monitored mouths. Plaintiffs argue that there is evidence that a lower dose and duration of the drug would have been possible. In their sur-reply, Plaintiffs further point to modified guidelines for dosing and duration issued at Mayo in May 2006. (Doc. No. 154, Ex. 6.) Defendant, on the other

hand, argues that because Plaintiffs have "entirely failed" to proffer evidence of feasible alternative design, their claim fails as a matter of law.

Here, the fact that issues of duration and dose are contested is not enough to create a genuine issue of material fact on a design defect claim. *See Sheffer v. Novartis*, Civ. No. 12-238, 2013 WL 5276558, at *8 (S.D. Ohio Sept. 18, 2013) (finding the plaintiff's arguments on dose and duration "woefully deficient" where plaintiff relied on the argument that "issues of dose and duration [were] contested"). Plaintiffs must offer evidence that addresses whether Aredia was unreasonably dangerous under the "reasonable care balancing test." *Bilotta*, 346 N.W.2d at 621-23. Plaintiffs first proffer a 2003 Novartis e-mail concerning the possibility of different dosages for Zometa. (Odette Aff. ¶ 3, Ex. 17.) However, this e-mail alone fails to address the "reasonable care balancing test" in any meaningful way—the fact that a different dose may be possible does not address wither a different dose of Aredia reduces the risk of ONJ without impairing Aredia's usefulness. *See Sheffer*, 2013 WL 5276558, at *8-9. Plaintiffs then attempt to supplement this sole piece of evidence by pointing to the revised guidelines for dosage and duration published by Mayo in 2006. (*Id.*, Ex. 6.) Again, the fact that Mayo revised its guidelines in 2006, however, fails to address the fundamental issues posed by the "reasonable balancing test." For example, Mayo's revised guidelines fail to address Novartis's actions, the "degree of care" taken by Novartis, whether there was an "unreasonable risk of harm," whether the "burden of the precaution" of recommending lower dosages and durations was possible at the time or constituted a safer design, or whether a lower dosage and duration would have been effective in preventing jaw

conditions. The same is true of an alleged failure to have doctors look in patients' mouths. Based on these two documents and an allegation that doctors should have been told to look in patients' mouths, no reasonable jury could conclude that Aredia was in an unreasonably defective condition that could have been reasonably remedied. Plaintiffs also point to no expert testimony supporting their allegations regarding dosage and duration.[10] Like in *Sheffer*, the Court here finds that "although [Kruzska] may very well have expert witness testimony to that effect, the Court is not obligated to dig through the record to uncover it, particularly in a case like this where the record is so voluminous. Judges need not paw over the files without assistance from the parties." *Sheffer*, 2013 WL 5276558, at *9 (internal citations and quotations omitted).

Based on the evidence before the Court, viewed in the light most favorable to Plaintiffs, the Court concludes that Plaintiffs have failed to point to evidence from which a reasonable jury could find the elements of a claim for design defect have been met. Plaintiffs' claim for negligent design defect is therefore dismissed, and Defendant's motion for summary judgment is granted as to this claim.

v. Punitive Damages

To obtain punitive damages, a plaintiff must prove that, in acting, the defendant "has knowledge of facts or intentionally disregards facts that create a high probability of injury to the rights or safety of others" and "deliberately proceeds to act in conscious or

[10] The Court recognizes that it is allowing certain dose and duration testimony from Dr. Marx. However, Plaintiffs fail to point to this testimony in their briefs, and more importantly, the allowed testimony does not create genuine issues of material fact as to the question of design defect.

intentional disregard of" or "with indifference to the high probability of injury to the rights or safety of others." Minn. Stat. § 549.20. Indifference must be malicious: "In order to impose the extreme punishment and deterrence of punitive damages, there must be a maliciousness, an intentional or willful failure to inform or act." *Beniek v. Textron, Inc.*, 479 N.W.2d 719, 723 (Minn. Ct. App. 1992).

Punitive damages are "an extraordinary remedy to be allowed with caution and within narrow limits." *J.W. ex rel. B.R.W. v. 287 Intermediate Dist.*, 761 N.W.2d 896, 904 (Minn. Ct. App. 2009) (citations omitted); *Lewis v. Equitable Life Assurance Soc'y of the U.S.*, 389 N.W.2d 876, 892 (Minn. 1986). A plaintiff must prove its claim by clear-and-convincing evidence. Minn. Stat. § 549.20. At the summary judgment stage, a court must ascertain whether a jury could reasonably find that plaintiff proved his case for punitive damages by the quality and quantity of evidence required by Minnesota law. *Morrow v. Air Methods*, 884 F. Supp 1353 (D. Minn. May 11, 1995).

Here, viewed in the light most favorable to the nonmoving party, Plaintiffs have sufficiently demonstrated the existence of specific facts in the record that create a genuine issue of fact for trial. *See Krenik*, 47 F.3d at 957. Plaintiffs point to a long list of evidence that, if true, could lead a reasonable jury to find that Defendant had acted with the requisite disregard for the safety of patients taking Aredia. For example, Plaintiffs present evidence of a number of instances that Defendant was made aware of concerns that bisphosphonates caused ONJ prior to the time that labels and information to doctors communicated that information. (*See* Germany Decl., Ex. 5A.) Plaintiffs also point to evidence that Defendant was aware doctors had seen patients with ONJ and were

concerned about a link to bisphosphonates. (*See, e.g.*, Germany Decl., Ex. 1.) The fact that some of the evidence to which Plaintiffs point was from after 2002 does not change this result; a document's weight is to be determined by the jury.

The Court also notes that this decision is consistent with other cases stemming from the MDL which have allowed plaintiffs to proceed to trial with punitive damages claims. *See, e.g.*, *Fussman v. Novartis Pharms. Corp.*, 509 Fed. Appx. 215 (4th Cir. 2013) (upholding a jury's punitive damages award) (unpublished); *see also Davids v. Novartis Pharms. Corp.*, Civ. No. 06-431, 2013 WL 5603824 (E.D.N.Y. Oct. 9, 2013) (upholding the jury's punitive damages award).

Therefore, having considered the pleadings and record before it, the Court finds that Plaintiffs have presented sufficient evidence to allow a reasonable juror to conclude that Plaintiffs have proved their case for punitive damages. Accordingly; the Court denies Defendant's motion for summary judgment as to punitive damages.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendant's Motion for Summary Judgment (Doc. No. [116]) is **GRANTED IN PART** and **DENIED IN PART** as follows:

    a. With respect liability for infusions post-January 2002, Defendant's motion is **GRANTED** to the extent that Plaintiffs seek liability for the effect of generic drugs on Kruszka, and **DENIED** to the extent that Plaintiffs seek liability stemming from Aredia's half-life and its effects.

b. With respect to Plaintiffs' failure to warn claims, Defendant's motion is **DENIED**.

c. With respect to Plaintiffs' design defect claim, Defendant's motion is **GRANTED**.

d. With respect to Plaintiffs' implied warranty claim, Defendant's motion is **GRANTED**.

e. With respect Plaintiffs' claims for punitive damages, Defendant's motion is **DENIED**.

2. Defendant's Motion to Exclude Expert Testimony (Causation Testimony) of Plaintiffs' Case-Specific Retained and Non-Retained Expert Witnesses (Doc. No. [94]) is **GRANTED IN PART** and **DENIED IN PART** as follows:

a. With respect to Dr. Gertz and specific causation testimony, Defendant's motion is **GRANTED**.

b. With respect to Dr. Juhlin and specific causation testimony, Defendant's motion is **GRANTED**.

c. With respect to Dr. Kraut and specific causation testimony, Defendant's motion is **DENIED**.

3. Defendant's Motion to Exclude Expert Testimony of Plaintiffs' Expert Dr. Robert Marx (Doc. No. [61]) is **GRANTED IN PART** and **DENIED IN PART** as follows:

a. Defendant's motion is **DENIED** with respect to Dr. Marx's testimony relating to: (1) pre-dental screening; (2) clinical trial patients

having BRONJ; (3) causation; and (4) biological mechanisms by which bisphosphonates cause ONJ.

b. With respect to Dr. Marx's testimony regarding dose and duration Defendant's motion is **GRANTED** to the extent his testimony is derived from specific studies and research, and is **DENIED** to the extent he opines on the results or efficacy of changing dose or duration.

c. With respect to Dr. Marx's testimony relating to "bad conduct," Defendant's motion is **GRANTED**.

Dated: May 12, 2014

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge