IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

CHRISTINE WINTER, Individually, and as Personal Representative of the Estate of RUTH BALDWIN,	)	
Plaintiff,	)	
v.	)	No. 06-4049-CV-C-MJW
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
Defendant.	)	

ORDER

Following a three-week jury trial, defendant Novartis Pharmaceuticals Corporation (NPC) filed a post-trial motion for judgment of acquittal as a matter of law, pursuant to Rule 50(b) of the Federal Rules of Civil Procedure, together with suggestions in support (docs. 241-42). Plaintiff Christine Winter, Personal Representative of the Estate of Ruth Baldwin, Deceased, has filed her suggestions in opposition (doc. 246). Defendant NPC has filed reply suggestions in support (doc. 251) and a notice of supplemental authority (doc. 253). The Court has carefully reviewed the filings of counsel and rules as follows:

I. Background

Aredia and Zometa are intravenous bisphosphonate medications prescribed to individuals with, among other things, cancers that have metastasized to bone. The drugs are prescribed to prevent devastating skeletal complications that frequently occur in patients with such cancers. These complications include pathologic fractures, spinal cord compression (which can result in paralysis), and hypercalcemia of malignancy (an elevation of calcium in the blood which can prove fatal). Dr. Robert Marx, plaintiff's expert, testified the drugs have played "a key role in the management of cancer-related bone disease," and are "extremely effective in halting the progression of both small and large bone metastases." In fact, he has written that these drugs "have dramatically extended life[,] reduced skeletal complications, reduced pain and thus

improved the quality of life for individuals with metastatic bone cancer." Since 1991, the United States Food and Drug Administration has approved these medications as safe and effective on six separate occasions and, each time, approved the labeling.

Although Aredia was first approved in 1991, plaintiff's evidence revealed that the connection between bisphosphonate medication and osteonecrosis of the jaw (ONJ) was first described in 2002. Late that year, Dr. Robert Marx published a textbook in which he included a chapter describing what he called "Avascular Necrosis" connected with Aredia. Marx Pathology Textbook, "Avascular Necrosis," PX 1092A. The following September 2003, Dr. Marx wrote a letter to the editor, which was published in the Journal of Oral and Maxillofacial Surgery, describing case reports of ONJ in Aredia and Zometa patients. PX 1089.

Three months later, in December 2003, NPC updated the medications' package insert (i.e., the label) to state that "[c]ases of osteonecrosis (primarily of the jaws) have been reported since market introduction" of these drugs. PX-1086D. In February 2004, NPC revised the Zometa label's discussion of ONJ to state that "[t]he majority of the reported cases are in cancer patients attendant to a dental procedure" and that "although causality cannot be determined, it is prudent to avoid dental surgery as recovery may be prolonged." Notably, however, evidence presented at trial revealed that NPC failed to include the information concerning the possibility of ONJ in the "Warnings" section of the label. Rather, the information was included in the "Post Marketing Experience" section of the label. PX-1086E. NPC again updated the Zometa label in August 2004 to include additional information about ONJ and sent out a letter to oncologists and oral surgeons that included the new language. See Sept. 24, 2004 Dear Doctor Letter, PX-0247.

In July 2003, Ruth Baldwin was diagnosed with recurrent breast cancer with metastases to her spine and liver. DX-RB-48. Mrs. Baldwin's oncologist, Dr. James Hueser, prescribed Aredia to Mrs. Baldwin beginning on July 24, 2003. DX-RB-24. Two months later, at her request, Dr. Hueser switched Mrs. Baldwin's prescription to Zometa. DX-RB-29. She received her last dose in October 2004. DX-RB-29.

On September 9, 2004, Mrs. Baldwin's dentist, Dr. Douglas Miller, extracted tooth #30.[1] A week later, Mrs. Baldwin reported that she could feel bone in the area where tooth #30 was removed. As a result, Dr. Miller referred her to Dr. Timothy Coyle, an oral surgeon. On October 26, 2004, Dr. Coyle diagnosed Mrs. Baldwin as having ONJ secondary to her bisphosphonate use. Dr. Coyle contacted Mrs. Baldwin's oncologist, Dr. Hueser, and informed him of his diagnosis of ONJ. As a result, Dr. Hueser immediately discontinued Mrs. Baldwin's prescription for Zometa.

Mrs. Baldwin filed her lawsuit in 2006. She alleged that NPC was liable due to a failure to provide adequate warnings of the risk of developing ONJ. Testimony from relatives and friends at trial revealed that Mrs. Baldwin suffered a rather slow and painful decline. In addition to the devastating effects of her cancer, Mrs. Baldwin also suffered a great deal of pain in her jaw as a result of the ONJ during the last year of her life. She could not eat solid foods because of the pain and risk of infection. She also lost a great deal of weight. At one point, Mrs. Baldwin removed a section of her dying jaw bone, described as the size of a quarter to a silver dollar, from her mouth while she was brushing her teeth. Her grandson, Brett Winter, witnessed the event and described for the jury the sharp pain he observed Mrs. Baldwin experience when she removed the bone from her jaw, and the "awful" smell, like a "dead animal smell," of the section of jaw bone that his grandmother held in her hand. (Tr. 1036.) Christine Winter, Mrs. Baldwin's daughter, testified she observed the gaping hole in her mother's mouth and described for the jury how the exposed jagged jaw bone would cut into her mother's mouth and tongue. Mrs. Baldwin died on November 4, 2006, from metastatic breast cancer. Mrs. Baldwin's daughter, Christine Winter, was later substituted as plaintiff following Mrs. Baldwin's death.

A jury trial began on March 20, 2012. Following the close of plaintiff's case on March 30, 2012, NPC filed a Rule 50(a) Motion for Judgment as a Matter of Law (doc. 206). On April 4, 2012, NPC rested and filed a renewed Motion for Judgment as a Matter of Law (doc. 213). Both motions were provisionally denied by the Court. On April 6, 2012, the jury returned a split

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[1]This tooth extraction occurred before NPC sent its September 24, 2004 "Dear Doctor Letter" to oncologists warning of the dangers of developing ONJ by patients having oral surgery and Aredia or Zometa.

verdict in favor of plaintiff on her negligent failure-to-warn claim and in favor of NPC on her strict liability claim. On April 9, 2012, judgment was entered for plaintiff for compensatory damages in the amount of $225,000 (doc. 222). The jury declined to award punitive damages.

II. Issues before the Court

In its Motion for Judgment as a Matter of Law (doc. 241), defendant NPC asserts that:

A. Plaintiff did not establish proximate cause because the prescribing oncologist, Dr. James Hueser, testified he did not read the package insert with the alleged inadequate warning; and

B. Plaintiff did not establish proximate causation because the alleged inadequate warning did not affect Mrs. Baldwin's treatment plan or outcome. NPC further alleges:

1. Plaintiff cannot recover as a matter of law based on an alleged failure to warn regarding pretreatment dental screenings; and

2. Plaintiff cannot recover as a matter of law based on an alleged failure to warn to avoid dental surgery.

Plaintiff disagrees and asserts there was sufficient evidence of proximate cause to sustain the jury's verdict in favor of plaintiff on her claim for negligent failure to warn. More specifically, plaintiff asserts that she introduced more than sufficient evidence for a reasonable jury to find that:

A. Defendant NPC negligently failed to adequately warn of the risk of developing osteonecrosis of the jaw (ONJ) from Aredia and Zometa; and

B. Defendant's failure to warn was the proximate cause of Mrs. Baldwin's ONJ. (doc. 246).

III. Legal Standard

A court should grant a Rule 50(b) motion if "as a matter of law the opposing party failed to make a case and a verdict in the movant's favor should have been directed." Davis v. Burlington N. Inc., 541 F.2d 182, 186 (8th Cir. 1976). The court must "draw all reasonable inferences in favor of the nonmoving party without making credibility assessments or weighing the evidence." Phillips v. Collings, 256 F.3d 843, 847 (8th Cir. 2001). "[J]udgment as a matter of law is appropriate when the record contains no proof beyond speculation to support [a]

verdict." Arabian Agric. Servs. Co. v. Chief Indus., Inc., 309 F.3d 479, 482 (8th Cir. 2002) (citation and quotation marks omitted).

Rule 50 allows a district court to resolve an issue against a party and to grant a motion for judgment as a matter of law only if the court finds that "a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a). As the Court of Appeals for the Eighth Circuit has explained:

> To sustain an entry of judgment as a matter of law, "[t]he evidence must point unswervingly to only one reasonable conclusion. This demanding standard reflects our concern that, if misused, judgment as a matter of law can invade the jury's rightful province."

Penford Corp. v. National Union Fire Ins. Co., 662 F.3d 497, 503 (8th Cir. 2011) (quoting Gardner v. Buerger, 82 F.3d 248, 251 (8th Cir.1996)); see also, Howard v. Missouri Bone & Joint Ctr., Inc., 615 F.3d 991, 995 (8th Cir. 2010); Duke v. Gulf & Western Mfg. Co., 660 S.W.2d 404, 409 (Mo. App. W.D. 1983) ("Sustaining a motion for a directed verdict is a drastic action and should only be done when all the plaintiff's evidence and reasonable inferences which may be drawn therefrom are so strongly against the plaintiff that reasonable minds cannot differ.").

IV. Legal Analysis

In order to prevail on her negligent failure-to-warn claim, plaintiff was required to present evidence sufficient to persuade the jury that:

> *First*, the defendant marketed and distributed Aredia and/or Zometa, and
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> *Second*, the defendant did not adequately warn of the risk of osteonecrosis of the jaw as a possible side effect of the use of Aredia and/or Zometa, and
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> *Third*, the defendant failed to use ordinary care to adequately warn Mrs. Baldwin's prescribing physician of the risk of osteonecrosis of the jaw of which defendant knew or should have known, and
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> *Fourth*, such failure directly caused or directly contributed to cause injury to Mrs. Baldwin.

See Instruction No. 24 - Negligence - Failure to Warn; M.A.I. (Civil) 25.09 (6th ed.) Verdict Directing-Products Liability-Negligent Failure to Warn; see also Johnson v. Medtronic, Inc., 365

S.W.3d 226 (Mo. Ct. App. 2012) ("To prevail on their failure to warn claim, the Johnsons had to establish proximate cause.").

In a negligent failure-to-warn case, whether or not a given warning is sufficient depends upon "the placement of the warning, its language and how it may or may not impress the average user." Johnson v. Medtronic, Inc. at 235 (quoting Brown v. Bay State Abrasives, 821 S.W.2d 531, 533 (Mo. App. 1991); Tennis v. General Motors Corp., 625 S.W.2d 218, 226 (Mo. App. S.D. 1981); see also Grady v. American Optical Corp., 702 S.W.2d 911, 917 (Mo. App. E.D. 1985) (quoting Tennis). "In evaluating these factors, the dangerous nature of the product, the form in which it is used, the burden to be imposed by requiring warnings and the likelihood that the particular warning will be adequately communicated to those who will foreseeably use the product must also be considered." Brown v. Bay State Abrasives, 821 S.W.2d at 533. "A warning, no matter how well stated or placed, is inadequate if it has no reasonable likelihood of reaching a foreseeable user and, thereby performing its intended function of risk reduction." Id. See also Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 146 (Mo. 1967) (Missouri courts have held that in cases involving manufacturers of prescription drugs, the manufacturer has "a duty to properly warn the doctor of the dangers involved and it is incumbent upon the manufacturer to bring the warning home to the doctor.").

A. Adequacy of the Warning

Here, the jury, as demonstrated by its verdict, agreed with plaintiff that NPC did not adequately warn of the risk of developing ONJ as a possible side effect of taking Aredia and/or Zometa. Evidence presented by plaintiff demonstrated that NPC did not take adequate steps to ensure that Dr. Hueser, Mrs. Winter's oncologist, and other oncologists prescribing Aredia and Zometa were adequately warned of the risks of developing ONJ when utilizing the two drugs. Evidence presented by plaintiff in the form of testimony from employees of NPC, expert witnesses, and in various NPC documents such as emails, did arguably reveal reluctance on the part of some key personnel at NPC to timely admit there was an association between the use of bisphosphonate drugs such as Aredia and/or Zometa and the development of ONJ in patients receiving dental surgery while taking the medications. Plaintiff presented sufficient evidence at trial that a reasonable jury could conclude that NPC was slow to respond to an obvious problem

and arguably tried to conceal or delay information concerning the risk of developing ONJ from the medical community and the public. While NPC vigorously disputed plaintiff's evidence on the adequacy and timing of the warning at trial, the jury decides the facts, and the Court must view the evidence for purposes of the Rule 50(b) motion in the light most favorable to the nonmoving party.

Plaintiff presented evidence demonstrating that in July 2003, when Mrs. Baldwin was first prescribed Aredia, there was no mention of the risks of developing ONJ anywhere in the Aredia and/or Zometa package insert (label). Plaintiff also introduced evidence arguably demonstrating that in August 2003, employees of NPC apparently instructed members of its sales force responsible for selling Aredia and/or Zometa in the State of Missouri, not to mention problems concerning the risk of developing ONJ when making sales calls to oncologists across the country, including Dr. Hueser.[2]

Dr. Robert Marx, plaintiff's causation expert and Chief of Oral Surgery at the University of Miami, formed an opinion that within a reasonable degree of medical certainty, Aredia and Zometa could cause ONJ in some users of the drugs, particularly in those patients who had undergone oral surgery while taking the drugs. He published his findings in a textbook he authored in December 2002. In September 2003, Dr. Marx wrote a letter to the editor, which was published in the Journal of Oral and Maxillofacial Surgery, describing specific cases in which ONJ had developed in patients using Aredia and Zometa.

Dr. Marx testified he first had contact with NPC concerning the ONJ problem in early June 2003. Dr. Marx testified he spoke with Dr. Peter Tarasoff, the Medical Director at NPC, and invited him to come to Florida to discuss his findings. Dr. Tarasoff and Dr. Diogini Maladorno, the Senior Safety Director for NPC, met with Dr. Marx in Florida on July 22, 2003, and discussed his findings. Dr. Marx testified that neither Dr. Tarasoff nor Dr. Maladorno

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[2]In spite of strong and compelling evidence linking bisphosphonate medications such as Aredia and Zometa to the development of osteonecrosis of the jaw in patients who had also undergone oral surgery while taking the drugs, NPC surprisingly continued to deny causation leading up to and during the initial stages of the trial.

mentioned to him that they had previously received information from Dr. Sal Ruggiero confirming his findings.

On December 5, 2003, Dr. Marx was invited to an Advisory Board meeting. There were 8 to 10 NPC representatives in attendance at the meeting, including Dr. Tarasoff and Dr. Maladorno. Dr. Marx made a presentation discussing the connection between ONJ and bisphosphonate drugs Aredia and Zometa. Dr. Ruggiero confirmed Dr. Marx's findings. A second Advisory Board meeting occurred in March 2004. NPC representatives asked the Board members to prepare a "white paper" describing the ONJ problem. According to Dr. Marx, Dr. Tarasoff was confrontational at the meeting and their discussion eventually turned into an argument.

In December 2003, NPC changed its package insert (label) and for the first time mentioned that some cases of ONJ had developed in patients using Aredia/Zometa. However, rather than putting the information in the "Warnings" section of the label, the information was put in the "Post Marketing Experience" section of the label where plaintiff asserted it would be less likely to be read. The new information in the label concerning ONJ also suggested there could be other causes of ONJ rather than the use of the two drugs. Plaintiff argued at trial that this represented an effort by NPC to mislead the reader.

Plaintiff also presented evidence suggesting that NPC could have provided a warning directly to Dr. Hueser and other oncologists through its frequent NPC-mandated sales representative visits to oncologists' offices. Plaintiff presented evidence that, in spite of evidence from its own scientists as well as other experts such as Dr. Marx and Dr. Ruggiero showing an association between bisphosphonate use and ONJ, NPC did not send a "Dear Doctor" letter to oncologists prescribing its medicines until September 24, 2004.

Dr. Hueser testified he would obtain information about new drugs such as Aredia and Zometa by reading numerous articles, primarily in the New England Journal of Medicine and Journal of Clinical Oncology. He also learned about new drugs from conversations with other oncologists in Central Missouri or at national oncology conferences. Dr. Hueser admitted that he never read the package inserts (labels) for either Aredia or Zometa. He testified that the print on the labels was so small that he could not read them and that he generally just threw them in the

trash can. The labels were entered into evidence at trial, confirming they were written in very small print. See Johnson v. Medtronic, Inc., 365 S.W.3d 226 (Mo. Ct. App. 2012) (In general, whether or not a given warning is sufficient depends upon "the placement of the warning, its language and how it may or may not impress the average user.")

Dr. Hueser testified the first time he heard about ONJ occurring in patients using Aredia or Zometa occurred when Dr. Timothy Coyle, Mrs. Baldwin's oral surgeon, called him and informed him that Mrs. Baldwin had contracted ONJ. Dr. Hueser immediately discontinued Mrs. Baldwin's use of Zometa at that time.

The evidence concerning the package insert in effect at the time of Mrs. Baldwin's initial prescription of Aredia in July 2003, proved that the insert did not contain any mention of the association between Aredia and ONJ. Indeed, there was no mention of ONJ at all. There was also no mention of the connection between Aredia and ONJ in the Physician's Desk Reference (PDR) for Aredia, which is a publication frequently reviewed by physicians. Dr. Hueser was familiar with the PDR and testified it had been around for a long time. Dr. Hueser also testified that he would read a monthly newsletter entitled "Medical Newsletter" on a monthly basis. The Medical Newsletter during the relevant period also did not contain any information concerning the risk of patients developing ONJ while taking Aredia or Zometa.

NPC also printed advertisements on medical publications frequently read by Dr. Hueser. The printed advertisements of NPC for the two drugs in the publications did not contain any warning or other cautionary language during the applicable time period when Dr. Hueser was treating Mrs. Baldwin. Dr. Hueser testified that he generally would not read the advertisements when reading the publications, but he could not help but see them when reading the monthly publications, in particular the Journal of Clinical Oncology.

Gordon Watkins, the NPC Sales Representative assigned to Dr. Hueser, testified and produced records reflecting that the first time he informed Dr. Hueser of the relationship between ONJ and Aredia and Zometa was on September 27, 2004. In addition, NPC's "Dear Doctor" letter, which Dr. Hueser testified he never received, although NPC records suggested otherwise, was not issued until September 24, 2004. This letter warned oncologists of the connection between ONJ and Aredia and Zometa. By that time, Mrs. Baldwin had been taking the two drugs

for fourteen months and both of her teeth, Nos. 30 and 31, had been removed by Dr. Doug Miller, her dentist. Mrs. Baldwin was diagnosed with ONJ on October 26, 2004, by Dr. Timothy Coyle, an oral surgeon. Based upon this evidence, the jury could easily have concluded the warnings were both insufficient and too late for Mrs. Baldwin.

NPC argues that because Dr. Hueser admitted he did not read the package inserts, then plaintiff cannot prevail. The Court disagrees. Based upon the evidence presented at trial, the jury could easily have concluded that NPC should have done more to alert the oncologists, including Dr. Hueser, of the dangers associated with the use of Aredia and Zometa by patients having oral surgery while taking the drugs. When Mrs. Baldwin first began taking Aredia, there was nothing at all in the package insert concerning ONJ. Later, when information was placed in the label, it was placed in a section ("Post Marketing Research" section) where it would be less likely to be read so as to adequately warn physicians of the dangers of prescribing the drugs to patients needing or undergoing dental surgery. Finally, the jury could easily have concluded that NPC should have taken greater steps to warn oncologists because of the strong evidence of causation linking ONJ to its two bisphosphonate drugs, Aredia and Zometa.

When considering all of the above evidence and reasonable inferences drawn therefrom relating to the issue of whether NPC adequately warned Dr. Hueser about the risks of ONJ, and viewing such evidence in the light most favorable to plaintiff, as a matter of law the Court finds that the evidence was clearly sufficient to support the jury's finding. The jury determined by its reasoned judgment that the warnings issued by NPC were inadequate. The Court will not second guess that finding.

B. Proximate Cause

NPC also contends plaintiff did not present sufficient evidence to support the jury's verdict on the issue of proximate cause. In order to establish proximate cause, plaintiff was required to prove that NPC's failure to warn directly caused or directly contributed to cause injury to Mrs. Baldwin. The Court finds as a matter of law that plaintiff did present sufficient evidence to support the jury's verdict.

Absolute certainty is not required in order for a plaintiff to prove a causal connection between a defendant's acts or omissions and plaintiff's injuries. See Howard v. Missouri Bone

& Joint Ctr, Inc., 615 F.3d 991, 996 (8th Cir. 2010) (citation omitted); Griggs v. Firestone Tire & Rubber Co., 513 F.2d 851, 861 (8th Cir. 1975). As the court in Griggs explained, "[c]ases involving an alleged failure to warn typically involve the element of forecasting what another's conduct would have been under supposed circumstances; certainty in such a forecast is not required." Griggs, 513 F.2d at 861. Rather, a plaintiff makes a "submissible case . . . if substantial evidence is presented that shows the injury is a natural and probable consequence of a defendant's" acts or omissions. Id. In any event, "[a]bsent compelling evidence which establishes the absence of causation, the causation question is for the jury." Id.; see also, Griggs, 513 F.2d at 861 ("The determination of proximate cause is ordinarily reserved for the jury, and may be shown by circumstantial evidence."). Here, the jury could easily conclude, based upon the evidence presented at trial, that NPC should have, and could have, done far more on a more timely basis to adequately warn Dr. Hueser and other oncologists prescribing Aredia and Zometa of the dangers of developing ONJ while taking the drugs. And the jury could also reasonably conclude that if NPC had done more to timely warn Dr. Hueser, Mrs. Baldwin would not have suffered her injury from ONJ.

Plaintiff did present evidence arguably demonstrating that a proper warning would have likely altered Dr. Hueser's behavior. Dr. Hueser immediately stopped prescribing Zometa to Mrs. Baldwin after Dr. Coyle diagnosed her with ONJ and never prescribed the drug to her again. In addition, Dr. Hueser stopped prescribing Zometa for all of his patients after Mrs. Baldwin and another patient contracted ONJ. Finally, while Dr. Hueser admitted that he never recommended to Mrs. Baldwin that she undergo a dental examination or avoid dental surgery before he prescribed Aredia and Zometa, it is a reasonable inference to conclude that he would have recommended that she get a complete dental examination and avoid oral surgery if he had been properly warned. Evidence from Dr. Coyle, Dr. Marx, and Dr. Kraut and NPC witnesses and documents demonstrated these warnings and screenings have now become the standard practice followed throughout the United States by oncologists and oral surgeons. Dr. Miller testified that after Dr. Coyle warned him of the risks of ONJ in October 2004, he changed his practices when treating patients to include a pre-Zometa complete dental screening and the avoidance of dental extractions while on Zometa.

NPC takes the position that the only way for it to adequately warn oncologists is to communicate the warnings in the package insert. The package insert is difficult to read because of the small print and the extremely large amount of information set forth in a relatively small piece of paper. The Court agrees with plaintiff that there were many other ways available for NPC to more quickly and efficiently communicate the problematic link between the two medications and the development of ONJ in patients undergoing dental surgery while taking the medications. In fairness, NPC eventually did take responsible steps to correct the shortcomings in the warnings once it became abundantly clear that Aredia and Zometa were causing ONJ in certain patients. Nevertheless, a reasonable jury could have concluded, under the facts that were presented during the trial, that NPC should have taken steps much sooner and more aggressively to warn oncologists, including Dr. Hueser, about the dangers of developing ONJ when taking the medications. Dr. Marx testified about the very positive results in cancer patients using Aredia and Zometa. Clearly, these two medications have improved the quality of life for cancer patients. However, Dr. Marx also testified that the problem with the development of ONJ in some patients had reached the epidemic level before NPC began to adequately warn of the dangers.

In its reply suggestions in support of its motion for judgment as a matter of law (doc. 251), NPC asserts that Dr. Hueser's decision not to read the package inserts is fatal to plaintiff's case. In support, NPC primarily relies upon Johnson v. Medtronic, Inc. However, the facts of that case are distinguishable from the facts before the Court. In Johnson v. Medtronic, Inc., at 231-32, the Missouri Court of Appeals placed significance on the fact that the plaintiffs were not contending that the manner in which the instructions were provided failed to effectively communicate to users of the LifePak 9P, a defibrillator. Such is not the case in this litigation. Here, plaintiff vigorously contended throughout the trial that the manner in which the instructions were provided by NPC was deficient. There were no warnings at all about ONJ in the package insert when Mrs. Baldwin initially began taking the drugs. And there was evidence presented at trial indicating that officials at NPC were aware or should have been aware of the ONJ problem during that period. Further, when NPC did begin including information about the possible development of ONJ in the package insert, the information was placed in the "Post Marketing Research" section of the label rather than in the "Warnings" section where it would be

more likely to be read. Plaintiff contended the information in the "Post Marketing Research" section also suggested there could be other causes of ONJ rather than Aredia or Zometa, making it more confusing for any oncologist prescribing the drug. Dr. Hueser also testified that the print was so small and so difficult to read that he found the package insert essentially of no value to him. The jury could reasonably have concluded that the manner in which the problems with ONJ were communicated by NPC was deficient and that there was some attempt by NPC to conceal from or lessen the full extent of the problem from oncologists, including Dr. Hueser.

In a failure-to-warn claim, a plaintiff must show that "the warning would have altered the behavior of the individuals involved in the accident. Moore v. Ford Motor Co., 332 S.W.3d 749, 762 (Mo. 2011) (quoting Arnold v. Ingersoll-Rand Co., 834 S.W.2d 192, 194 (Mo. Banc 1992). In this regard, Missouri supplies the presumption that a warning, if provided, will be read and heeded. Id. (citing Arnold, 834 S.W.2d at 194). "In this instance, the term 'presumption' is used to mean 'makes a prima facie case,' i.e., creates a submissible case that [a proper] warning would have been heeded." Tune v. Synergy Gas Corp., 883 S.W.2d 10, 14 (Mo. 1994). Here, there was no warning at all provided initially. Plaintiff contended at trial that the manner in which the warning was eventually conveyed was grossly deficient.

NPC also contends that it cannot be found negligent as a matter of law because its March 2003 label change adequately warned of the need to avoid dental extractions while taking Zometa and was therefore legally sufficient as a matter of law. Plaintiff responds that NPC ignores the fact that she offered substantial evidence that the content, placement, mode and location of NPC's March 2003 warning was inadequate. Plaintiff further contends that the adequacy of NPC's warnings based on what NPC knew or should have known were properly submitted to the jury. The Court agrees with plaintiff. There was sufficient evidence presented to find, as a matter of law, that the March 2003 warning was inadequate. If the warning had been more adequately conveyed by NPC, Dr. Hueser may very well have been made aware of the ONJ problem and Dr. Miller may not have ever removed tooth #30, or the prescription for Zometa could have been discontinued for an amount of time until the dental surgery could be safely performed.

V. Conclusion

Viewing the evidence presented a trial in the light most favorable to plaintiff, the Court believes as a matter of law that the evidence presented was sufficient to support, and the jury here could reasonably have reached, the verdict that it eventually returned in favor of plaintiff.

IT IS, THEREFORE, ORDERED that defendant NPC's motion for judgment as a matter of law is DENIED. [241]

Dated this 3rd day of August, 2012, at Jefferson City, Missouri.

/s/ Matt J. Whitworth

MATT J. WHITWORTH
United States Magistrate Judge