IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

CHRISTOPHER RUTZ, Plaintiff, vs. NOVARTIS PHARMACEUTICALS CORP., Defendant.	Case No. 12-CV-0026-MJR

MEMORANDUM AND ORDER

REAGAN, District Judge:

I. Introduction

Plaintiff Christopher Rutz[1] brings this strict liability action against Defendant Novartis Pharmaceuticals Corporation (NPC), alleging that Carolyn Rutz (Rutz), developed osteonecrosis of the jaw (ONJ) as a result of Zometa infusions prescribed by her oncologist to treat her breast cancer and to prevent the effects of skeletal-related events.[2] Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure, NPC moves the Court to grant summary judgment on all claims (Doc. 86). NPC contends that: (1) Plaintiff has no admissible evidence that Rutz developed the injury alleged in this case – bisphosphonate-related osteonecrosis of the jaw (BRONJ); (2) Plaintiff has no evidence that NPC's warnings were inadequate; (3) even if Plaintiff could prove that NPC's warnings were inadequate, he has no evidence that a different warning would have changed the outcome of Rutz's alleged injuries.

[1] Christopher Rutz was substituted as Plaintiff in this litigation upon the death of his mother, Carolyn Rutz.
[2] Manufactured and sold by NPC, Zometa was approved by the FDA in 2001 and remains on the market today as an FDA-approved drug with FDA-approved labeling.

Plaintiff responds that NPC's motion should be denied because a jury could find that Zometa caused Rutz's injury based on Plaintiff's competent medical evidence of causation. Plaintiff states that Dr. Alan Schwimmer and Dr. Michael Hesterberg, oral and maxillofacial surgeons, testified that Zometa caused Rutz's ONJ. Plaintiff submits that he can show that Zometa's warning was inadequate and that an adequate warning about BRONJ could have changed the outcome of Rutz's injuries. Plaintiff contends that he can prove that Dr. Guillermo Rodriguez, Rutz's oncologist, was not a learned intermediary and, consequently, there is a "heeding presumption" that Dr. Rodriguez would have heeded an adequate warning about ONJ. Moreover, according to Plaintiff, there is circumstantial evidence that Dr. Rodriguez and Rutz would have acted differently with an adequate warning about ONJ.

NPC's motion is fully briefed, and oral argument was held on November 9, 2012. Analysis begins with reference to the standard governing this Court's review of the summary judgment motion.

II. Legal standard

Summary judgment is appropriate where the pleadings, discovery materials, and any affidavits show that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law. ***Turner v. The Saloon, Ltd.*, 595 F.3d 679, 683 (7th Cir. 2010); *Breneisen v. Motorola, Inc.*, 512 F.3d 972 (7th Cir. 2008), *citing Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).**

In ruling on a summary judgment motion, the district court must construe all facts in the light most favorable to, draw all legitimate inferences in favor of, and resolve all doubts in favor of the non-moving party. ***National Athletic Sportswear, Inc. v. Westfield Ins. Co.*, 528**

F.3d 508, 512 (7th Cir. 2008). ***Accord Reget v. City of La Crosse,*** **595 F.3d 691 (7th Cir. 2010).**

When the non-moving party bears the burden of proof, though, he must demonstrate the existence of a genuine fact issue to defeat summary judgment. ***Reget,*** **595 F.3d at 695.** To survive summary judgment, the non-movant must provide admissible evidence on which the jury or court could find in his favor. ***See Maclin v. SBC Ameritech,*** **520 F.3d 781, 786 (7th Cir. 2008).**

In deciding a summary judgment motion, the court may not evaluate the weight of the evidence, judge the credibility of witnesses, or determine the truth of the matter. The court's only role is to determine whether there is a genuine issue of triable fact. ***National Athletic,*** **528 F.3d at 512*, citing Doe v. R.R. Donnelley & Sons Co.,* 42 F.3d 439, 443 (7th Cir. 1994).** As succinctly stated by the Seventh Circuit Court of Appeals, "There is no genuine issue of material fact when no reasonable jury could find in favor of the nonmoving party." ***Van Antwerp v. City of Peoria, Ill.,*** **627 F.3d 295, 297 (7th Cir. 2010*, quoting Brewer v. Bd. of Trs. of the Univ. of Ill.,* 479 F.3d 908, 915 (7th Cir. 2007).**

Stated another way, summary judgment is the "put up or shut up" moment in litigation – the point at which the non-movant must marshal and present to the court the admissible evidence which he contends will prove his case. ***Goodman v. National Sec. Agency, Inc.,*** **621 F.3d 651, 654 (7th Cir. 2010) (citations omitted).** With these principles in mind, the Court turns to the motion in the instant case.

III. Discussion

A. Factual background

The following facts regarding Rutz's medical and dental history are undisputed. Rutz was diagnosed with breast cancer in 1997. Initially treated with radiation and chemotherapy, Rutz underwent a left breast mastectomy in April 1998. She developed a local recurrence as well as a malignant mass in her right breast. She again underwent chemotherapy followed by treatment with Tamoxifen.[3] In January 2002, Rutz had a bone scan that demonstrated a metastatic lesion of the left femur. She began Zometa therapy in June 2002, which she continued through August 2005. During much of the time that Rutz was receiving chemotherapy, she was also being treated with Decadron, a corticosteroid, taking about 15 doses a month between December 1997 and February 2002.

In April 2003, Dr. Ron Thouvenot, Rutz's family dentist, extracted six maxillary (upper jaw) teeth and inserted a maxillary prosthesis. Following extraction, Rutz developed non-healing wounds of teeth #7 and #8. In September 2003, Rutz was referred to Dr. Hesterberg for further evaluation. Dr. Hesterberg performed an alveoplasty[4] in the right and left maxillary quadrants. Rutz underwent multiple procedures by Dr. Hesterberg between November 2003 and June 2006. A September 2004 biopsy demonstrated boney sequestra[5] with inflammation consistent with acute and chronic osteomyelitis. Referred to Dr. Omer Badahman, an infectious disease specialist, for further evaluation, Rutz was seen by him from August 2005 through March 2006. During this period, she underwent extensive antibiotic treatment. Dr. Badahman's last entry in Rutz's medical record indicates osteonecrosis of the maxilla secondary to Zometa

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[3] Tamoxifen citrate is a nonsteroidal oral antiestrogen also having weak estrogenic effects; used as an antineoplastic in the prophylaxis and treatment of breast cancer. http://dorlands.com (visited December 10, 2012).

[4] Alveoplasty is conservative contouring of the alveolar process (the portion of bone in either the maxilla or the mandible that surrounds and supports the teeth), in preparation for immediate or future denture construction. http://dorlands.com (visited December 10, 2012).

[5] Sequestra are pieces of dead bone that have become separated during the process of necrosis from the sound bone. http://dorlands.com (visited December 10, 2012).

therapy, as well as a superimposed soft tissue infection. A February 2006 maxillofacial CT scan documented the presence of a 12 mm x 13 mm area of boney destruction involving the maxilla immediately below the maxillary spine. Rutz's metastatic disease progressed, and she passed away from breast cancer on August 15, 2011.

B. Causation

NPC asserts that Plaintiff lacks evidence to establish that Zometa caused Rutz's alleged injuries. First, according to NPC, Plaintiff's own specific causation expert admitted that his records showed that Rutz's condition did not meet the accepted definition of BRONJ. Second, Plaintiff has no evidence to rule out other risk factors, such as osteomyelitis or metastatic cancer, that may have been the sole cause of Rutz's ONJ. And, third, without admissible expert testimony, Plaintiff's case fails.

Plaintiff responds that a jury could find that Zometa caused Rutz's injury because competent medical evidence of causation supports this conclusion. Plaintiff submits that Dr. Schwimmer and Dr. Hesterberg testified that Zometa caused Rutz's ONJ to a reasonable degree of medical certainty. Plaintiff maintains that these experts used a differential diagnosis to arrive at their opinion that Zometa caused Rutz's injury, and that differential diagnosis is a well-known and widely-accepted methodology in the Seventh Circuit. According to Plaintiff, NPC's argument is merely a rehash of its *Daubert* motion, and the identification of flaws in reliable scientific evidence is the role of cross-examination.[6]

As the Illinois Court of Appeals for the Third District explained regarding medical expert opinion testimony,

[6] On December 7, 2012, the Court denied NPC's motion to exclude the testimony of Dr. Hesterberg and Dr. Schwimmer (Doc. 126).

> To be probative on the issue of causation, a medical expert is not required to give an opinion regarding a *specific* cause. Rather, a medical expert is permitted to testify to what might or could have caused an injury, despite any objection that the testimony is inconclusive. Testimony from a physician regarding what might or could have caused an injury is merely a medical opinion given on facts assumed to be true. For evidence to be relevant, it need only tend to make the existence of any fact more probable or less probable than it would otherwise be.

***Hahn v. Union Pacific R. Co.*, 816 N.E.2d 834, 841 (Ill.App.Ct. 2004) (internal citations and citation omitted) (emphasis in original).** The medical expert testimony on causation, however, may not be "contingent, speculative or merely possible." ***Northern Trust Co. v. Univ. of Chicago Hospitals and Clinics*, 821 N.E.2d 757, 768 (Ill.App.Ct. 2004) (citations omitted)**. An expert opinion held to a reasonable degree of medical certainty provides a sufficient basis for a jury finding that causation was proven. *Id.* (citations omitted). "Unquestionably, the relative weight, sufficiency and credibility assessed to medical expert testimony is 'peculiarly within the province of the jury[.]'" ***Id.* at 769 (citations omitted)**.

Probative on the issue of causation is Dr. Schwimmer's opinion that Rutz had BRONJ and that Zometa therapy was the cause of her ONJ and development of osteomyelitis. Additionally, Dr. Schwimmer opined that the extraction sites involved with the removal of her teeth would have resolved without significant complication, despite her history of smoking and Decadron therapy, if she had not been on Zometa.

NPC asserts that Rutz's condition did not meet the American Academy of Oral and Maxillofacial Surgeons' (AAOMS) definition of BRONJ, strongly disputing that Rutz met the first element of the test - that she had 8 weeks of exposed bone. But Dr. Schwimmer disagreed, stating that, based on his clinical experience, 4 to 5 weeks of exposed bone was the minimum. Doc. 74-9, Schwimmer Dep., 244:13-25. He agreed, however, that Dr. Thouvenot

did not document the existence of exposed bone in May, July, August or October 2003, stating, "We don't know exactly when the bone was exposed or whether she developed exposed bone."

A failure to document exposed bone does not doom Plaintiff's case. Rutz's condition predates the AAOMS's definition of BRONJ. Since exposed bone was not yet known to be an indicator of BRONJ, records created at that earlier date would not necessarily reflect whether exposed bone was present. So, for Dr. Schwimmer to diagnose BRONJ based on his clinical experience was not unreasonable. Given that Rutz may have had exposed bone which was not recorded, it would be unfair to permit NPC to use the absence of a record to conclude that BRONJ was not present, and then to obtain summary judgment on that basis. ***See Deutsch,* 768 F.Supp.2d at 449-50**. A jury could determine that other indicia of BRONJ – such as non-healing wounds - made it likely that exposed bone was present. Moreover, as the Court decided in its December 7 Order, Dr. Schwimmer's testimony is admissible and may be challenged on cross-examination. His disagreement with the AAOMS standard does not provide a basis for excluding his testimony or granting summary judgment on this issue.

Because genuine issues of material fact exist with respect to causation, summary judgment is not warranted.

C. Adequacy and timeliness of NPC's warnings

NPC asserts that even if Plaintiff could establish that Rutz's treatment with Zometa caused her ONJ, he lacks the evidence required to prove that NPC "knew or should have known" at the relevant times that Zometa could cause ONJ but failed to warn of that fact. NPC argues that, under the learned intermediary doctrine, it was required to warn only Rutz's prescribing physician, who acts as a "learned intermediary" between NPC and Rutz. NPC submits that it received its first Adverse Event Report (AER) on December 6, 2002, nearly six

months after Rutz began treatment with Zometa. NPC states that it promptly submitted the AER to the FDA in compliance with federal regulations and also timely notified the FDA about additional AERs. According to NPC, after it collected adequate data, it voluntarily changed its warnings to communicate the occurrence of jaw problems in patients receiving Zometa. NPC submits that it amended the Zometa label in September 2003 as well as in February and September 2004. Furthermore, NPC states that it sent a letter on September 24, 2004, to thousands of doctors – including Rutz's oncologist – warning, among other things, that "[w]hile on treatment, these patients should avoid invasive dental procedures if possible." In sum, NPC asserts that Plaintiff has no evidence that, based on the available knowledge, NPC should have or could have acted more quickly to implement an appropriate warning.

Plaintiff responds that a jury could find that Zometa's warning was inadequate and that adequacy of warning is usually a jury question. Plaintiff asserts that his experts will opine that NPC knew about the risk of ONJ long before it amended its warning and sent the letters notifying doctors of the risk. Plaintiff contends that evidence presented to the MDL court shows that NPC knew its Zometa warning was inadequate. Plaintiff submits that the MDL court found that the plaintiffs had submitted a "myriad of evidence" to rebut the statutory presumption (under Florida law) of adequacy when the drug is FDA-approved, such that a jury could find that the Zometa warning was inadequate. Plaintiff notes that Illinois law has no such presumption.

As this Court previously found, precedent teaches that, '[a]s most commonly defined, the [law of the case] doctrine ... posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages *in the same case.*" ***Jarrard v. CDI Telecommunications, Inc.*, 408 F.3d 905, 912 (7th Cir. 2005), *quoting* *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 815–16 (1988) (citation omitted)**

(emphasis added in *Jarrard*); *see also id.* at 816 ("[T]he doctrine applies as much to the decisions of a coordinate court in the same case as to a court's own decisions."). "The doctrine 'is a rule of practice, based on sound policy that, when an issue is once litigated and decided, that should be the end of the matter.'" ***Id.*** **(citations omitted)**.

Finding that genuine issues of material fact remained, the MDL court (Chief District Judge Todd J. Campbell) denied NPC's motion for summary judgment as to the adequacy of NPC's Zometa warnings. Judge Campbell observed, "Generally, whether a warning is adequate is an issue of fact to be determined at trial." ***In re Aredia and Zometa Prods. Liability Litigation*, 2009 WL 2496873, at *2 (M.D.Tenn. 2009), *quoting Figueroa v. Boston Scientific Corp.*, 254 F.Supp.2d 361, 370 (S.D.N.Y. 2003).** This same presumption holds true in Illinois where courts have found that "[i]n a strict liability case, the adequacy of the warning usually presents a jury question." ***Hernandez v. Schering Corp.*, 958 N.E.2d 447, 455 (Ill.App.Ct. 2011), *citing Palmer v. Avco Distributing Corp.*, 412 N.E.2d 959 (1980)**. This issue having been previously been litigated before and decided by the MDL court, it is the law of the case and continues to govern this issue in the current stage of the case.

If the Court were to consider the adequacy and timeliness of NPC's warnings beyond the MDL court's decision, it would arrive at the same conclusion – that these are jury questions. For example, NPC states that it voluntarily changed its warnings after it collected adequate data. This statement, standing alone, presents obvious questions of adequacy and timeliness such that summary judgment is not warranted. NPC waited approximately 10 months after receiving the first AER to notify the FDA that it was revising the Adverse Reactions section of Zometa labeling to include language reflecting reports of ONJ associated with the use of intravenous bisphosphonates. And it waited approximately 22 months before sending its "Dear

Doctor" letter notifying prescribing doctors of the label change. To rebut Plaintiff's claims, NPC must establish before the trier of fact that its course of action was appropriate, *i.e.*, that its judgment that a particular quantum of data was needed and was unavailable until a given date such that its warnings were adequate and timely. NPC must refute expert testimony that it knew or should have known at an earlier date that Zometa could cause ONJ and delayed amending its warning and notifying the FDA.

For these reasons, the Court concludes that summary judgment is not warranted on the adequacy and timeliness of NPC's warnings.

D. Whether a different warning would have prevented Rutz's BRONJ or otherwise changed the outcome of her treatment

NPC asserts that Plaintiff cannot prove that the alleged inadequate warning was the proximate cause of Rutz's jaw injury. NPC points to the testimony of Dr. Rodriguez, Rutz's oncologist who prescribed Zometa for her. Dr. Rodriguez testified that he continues to prescribe bisphosphonates (Zometa and Xgeva) for people with bony metastases and that using a bisphosphonating agent for a patient with bony metastasis remains the standard of care. Doc. 106-5, Rodriguez Dep. 47:16-19; 48:16-49:6. NPC contends that Plaintiff has no evidence that Rutz would have refused treatment with Zometa if she had been warned of the risk of ONJ or that a warning about the risk of ONJ would have changed the outcome of her injuries. NPC also argues that there is no evidence that a recommendation to see a dentist before commencing bisphosphonate therapy would have made any difference since Rutz saw her dentist regularly. Additionally, NPC maintains that there is no evidence that the April 2003 extractions, which allegedly precipitated the development of Rutz's ONJ, could have been addressed before she began Zometa, nearly a year earlier. NPC sums up that without expert evidence that Zometa would not have been prescribed or that Rutz's medical or dental treatment would have changed

in a way that would have prevented her jaw problems, Plaintiff cannot prove that any alleged failure to warn by NPC caused Rutz's injuries.

Plaintiff argues that a jury could find that an adequate warning would have changed the outcome because (1) Dr. Rodriguez was not a learned intermediary; (2) it is presumed that Dr. Rodriguez would have heeded an adequate warning about ONJ; and (3) circumstantial evidence from Dr. Rodriguez and Rutz shows that the outcome would have been different with an adequate warning.

To state a failure-to-warn claim against a drug manufacturer under Illinois law, a plaintiff must establish that the defendant had a duty to warn, that the defendant knew or should have known that the drug could cause the plaintiff's injury, that the failure to provide the necessary information made the warning inadequate, that the drug was "'defective' and that this defect was the proximate cause of plaintiff's injuries." ***N. Trust,* 572 N.E.2d at 1037**. Under the "learned intermediary" doctrine, a drug manufacturer has a duty to warn the prescribing doctor, rather than the patient, of any known risks. ***Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002)**. It is then the responsibility of the doctor, using his medical judgment, to convey the warnings to the patient. ***Id.*** "Doctors who have not been *sufficiently* warned of the harmful effects of a drug cannot be considered 'learned intermediaries' and the adequacy of warnings is a question of fact, not law, for the jury to determine…." ***Id.* at 43*, quoting Proctor v. Davis,* 682 N.E.2d 1203 (Ill. 1997) (emphasis added in *Hansen*)**. So, it is a jury question whether a warning sufficiently apprised doctors of the risks associated with the use of a drug. ***N. Trust,* 572 N.E.2d at 1037**. And, as applied herein, it is a jury question whether NPC's warning sufficiently apprised Dr. Rodriguez of the risk of ONJ associated with Zometa, such that he could be considered a learned intermediary.

If Dr. Rodriguez were considered a learned intermediary, the issue of whether a "heeding presumption" applies has not been clearly addressed by the Illinois Supreme Court. But the Illinois Appeals Court for the First District offers some guidance, stating that where the presumption applies, a court "presumes that warnings, if given, will be heeded and followed and that medical practitioners will act competently." ***Mahr v. G.D. Searle & Co.*, 390 N.E.2d 1214, 1233 (Ill.App.Ct. 1979) (applying Texas law)**. The Court also finds persuasive the analysis of Judge Bucklo who assumed the existence of a heeding presumption in ***Erickson v. Baxter Healthcare, Inc*., 151 F.Supp.2d 952 (N.D.Ill. 2001).** In ***Erickson***, the defendants argued that the causal chain was broken because the plaintiff could not show that his doctors were not independently aware of the risk or that they would not have treated him in the same way even if they knew the risk. **151 F.Supp.2d at 970**. Judge Bucklo reasoned that this argument presumed that adequate warnings were given, which she had already decided could not be resolved at that stage of the proceedings. ***Id.*** She concluded, "In any event, the plaintiffs are entitled at this stage to a presumption that a learned intermediary would have heeded the warnings given." ***Id., citing Mahr*, 390 N.E.2d at 1233**.

The undersigned Judge has also decided that whether adequate warnings were given cannot be resolved at this stage of the proceedings. Moreover, the "heeding presumption" is a natural result of or corollary to the learned intermediary doctrine. So, the Court concludes that if Dr. Rodriguez were considered a learned intermediary, there is a presumption that he would have heeded an adequate warning about ONJ.

Dr. Rodriguez's testimony shows that he did not know of the risk of ONJ when he prescribed Zometa for Rutz in June 2002. He warned Rutz of other risks, such as flu-like symptoms and bone pains. Doc. 106, Exh. 5, Rodriguez Dep. 30:18-23. NPC warned Dr.

Rodriguez of the risk of ONJ associated with Zometa in September 2004. Dr. Rodriguez stopped Rutz's Zometa therapy in 2005. Under the heeding presumption, Plaintiff does not have to prove what Dr. Rodriguez might or might not have done if given an adequate warning about the risk of ONJ.

Furthermore, the record shows that since learning of the link between Zometa and ONJ in September 2004, Dr. Rodriguez changed his advice to patients to whom he is recommending bisphosphonates to include going over the risks of ONJ with them, encouraging them to see a dentist if they have not done so within the past six months and encouraging them to have any necessary dental procedures done before starting on bisphosphonates. Rodriguez Dep., 78:19-79:6.

Lastly, Plaintiff argues that circumstantial evidence from Dr. Rodriguez and Rutz shows that the outcome would have been different with an adequate warning. Rutz testified that she would not have taken Zometa if Dr. Rodriguez had warned her of the risk of ONJ. She testified that a less than one percent risk that she would have jaw problems, "a dead jaw," would have tipped the scale, and she would have said "no, I'm not taking that." Doc. 106, Exh. 6, Rutz Dep., 122:22-124:10. NPC asserts that this is a self-serving statement made by a plaintiff after the commencement of her lawsuit without evidentiary support.

"'Self-serving' deposition testimony *may* satisfy a party's evidentiary burden on summary judgment. ***Whitlock v. Brown,* 596 F.3d 406, 411 (7th Cir. 2010), *citing Payne v. Pauley,* 337 F.3d 767, 772 (7th Cir. 2003) (emphasis in original).** The ***Whitlock*** court explained that, under the ***Payne*** analysis, "the sufficiency of a 'self-serving' statement depends on whether the statement is based on personal knowledge and whether it is grounded in observation as opposed to mere speculation." ***Id.*** Rutz's testimony passes this test because she

explained, reasonably, that she did not want another "porta cath" and that if she would have had another excuse – even a small chance of incurring jaw problems - for avoiding the cath, she would have refused the treatment. Rutz Dep., 123:2-124:10. Rutz was not speculating, and her testimony was based on personal knowledge.

For these reasons, the Court concludes that summary judgment is not warranted on the issue of whether a different warning would have prevented Rutz's BRONJ or changed the outcome of her treatment.

IV. Conclusion

Finding that genuine issues of material fact remain for trial, the Court **DENIES** NPC's motion for summary judgment (Doc. 86).

IT IS SO ORDERED.

DATED this 17th day of December, 2012

s/Michael J. Reagan
MICHAEL J. REAGAN
United States District Judge