IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

KAREN ROWLAND, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORP., Defendant.	)	Civil Action No. 2:12-cv-01474 Judge Mark R. Hornak

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GEORGE MACHEN and STACY MACHEN, Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORP., Defendant.	)	Civil Action No. 2:12-cv-01476 Judge Mark R. Hornak

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MICHELLE PRATT ORR, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORP., Defendant.	)	Civil Action No. 2:12-cv-01715 Judge Mark R. Hornak

OPINION

Mark R. Hornak, United States District Judge

Plaintiffs Karen Rowland ("Ms. Rowland"), George Machen ("Mr. Machen"), Stacy Machen ("Mrs. Machen"), and Michelle Pratt Orr ("Mrs. Orr") bring strict liability, negligence, and breach of warranty claims against the Defendant, Novartis Pharmaceuticals Corporation ("NPC"), alleging that they or their spouse developed a painful and permanently disfiguring condition commonly known as osteonecrosis of the jaw ("ONJ") as a result of using Zometa, a prescription medication designed, manufactured, and marketed by NPC and used for the purpose of managing metastatic bone cancer. Pending before the Court are NPC's Motions for Summary Judgment, which were originally filed as part of multi-district pre-trial proceedings in the Middle District of Tennessee.[1]

The Court has considered the Plaintiffs' Complaints, ECF 2:12-cv-01474-MRH, No. 1, ECF 2:12-cv-01476-MRH, No. 1, and ECF 2:12-cv-01715-MRH, No. 1, Defendant's Motions for Summary Judgment, (originally filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:08-cv-00131, at ECF No. 24; Case No. 3:10-cv-00830, at ECF No. 31; Case No. 3:07-cv-00472, at ECF No. 29), and Briefs in Support, (originally filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:08-cv-00131, at ECF No. 25; Case No. 3:10-cv-00830, at ECF No. 32; Case No. 3:07-cv-00472, at ECF No. 30), Defendant's Statements of Material Facts, (ECF Nos. 35, 37, and 39), and Plaintiffs' Responses in Opposition, (originally filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:08-cv-00131, at ECF No. 37; Case No. 3:10-cv-00830, at ECF No. 41; Case No. 3:07-cv-00472, at ECF No. 38), Plaintiffs' Responses to the Motions for Summary Judgment, (originally filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:08-

[1] Although originally filed in the District of Columbia and the Southern District of New York, these cases were conditionally transferred to the Middle District of Tennessee ("the MDL court") for coordinated pretrial proceedings pursuant to the Multi-District Litigation Act, 28 U.S.C. § 1407. While the cases remained in the MDL court, NPC filed motions for summary judgment. The MDL court later remanded the cases to this Court with the summary judgment motions still pending. ECF Nos. 4, 9. The cases have been consolidated here for pretrial proceedings at ECF Docket No. 2:12-cv-1474-MRH.

cv-00131, at ECF No. 35; Case No. 3:10-cv-00830, at ECF No. 39; Case No. 3:07-cv-00472, at ECF No. 39), Defendant's Reply Briefs, (originally filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:08-cv-00131, at ECF No. 47; Case No. 3:10-cv-00830, at ECF No. 51; Case No. 3:07-cv-00472, at ECF No. 43), Plaintiffs' Supplemental Response, ECF No. 45, and Defendant's Replies, ECF Nos. 48-50.[2] For the reasons that follow, the Court will grant in part and deny in part the Motions for Summary Judgment.

I. BACKGROUND

A. History of Bisphosphonate-Related Osteonecrosis of the Jaw ("BRONJ")

These lawsuits involve Zometa, a Food and Drug Administration ("FDA") approved intravenous bisphosphonate ("IV BP") prescription drug used to prevent bone destruction that frequently occurs in cancer patients when the disease has metastasized to their bones. Defendant's Statement of Material Facts as to Ms. Rowland ("RSOF"), ECF No. 39, ¶¶ 1-3; Rowland Compl. ("RC") ¶ 6. The reported clinical value of using IV BPs includes reducing skeletal complications, reducing pain, and improving the patient's quality and duration of life. RSOF at ¶ 51. Plaintiffs allege that they developed ONJ, a permanently disfiguring and painful condition that causes bone necrosis (death) and may result in complete loss of the jaw bone. RC ¶ 1. More specifically, Plaintiffs claim they developed a form of ONJ caused by IV BPs, interchangeably referred to by the parties as bisphosphonate-related ONJ ("BRONJ"), bisphosphonate-induced ONJ ("BIONJ"), or bisphosphonate ONJ ("BONJ")[3], as a result of their Zometa use. *Id.*

[2] The Court has also reviewed the parties' Notices of Supplemental Authority, ECF Nos. 105-06, 116, 125, 128, and various filings in response, ECF Nos. 115, 118-19.

[3] In the interest of clarity, the Court will consistently refer to this condition as BRONJ.

NPC is a pharmaceutical corporation that produces and distributes Zometa and Aredia, the "first generation" precursor to Zometa. RC ¶¶ 4, 6. The FDA initially approved Zometa in August 2001 for treatment of patients with hypercalcemia of malignancy and then in February 2002 approved it for treatment of patients with multiple myeloma and bone metastases from solid tumors, including breast cancer. RSOF ¶¶ 1-2. NPC received an adverse event report of ONJ from a dentist in Florida in December 2002. *Id.* ¶ 7. In September 2003, Dr. Robert Marx authored the first published case report addressing ONJ in IV BP users. *Id.* ¶ 33. On September 26, 2003, NPC informed the FDA that it was revising the Zometa labeling to include the following language in the Adverse Reactions section of the label:

> Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa® or other bisphosphonates, to concomitant drugs or other therapies (e.g. chemotherapy, radiotherapy, corticosteroid), to patient's underlying disease, or to other co-morbid risk factors (e.g. anemia, infection, pre-existing oral disease).

Id. ¶ 14. In February 2004, NPC revised the Post-Marketing Experience portion of the Zometa label as follows:

> Cases of osteonecrosis (primarily involving the jaws) have been reported in patients treated with bisphosphonates. The majority of the reported cases are in cancer patients attendant to a dental procedure. Osteonecrosis of the jaws has multiple well documented risk factors including a diagnosis of cancer, concomitant therapies (e.g. chemotherapy, radiotherapy, corticosteroids) and co-morbid conditions (e.g. anemia, coagulopathies, infection, pre-existing oral disease). Although causality cannot be determined, it is prudent to avoid dental surgery as recovery may be prolonged.

Id. ¶ 20.

In September 2004, NPC revised the Zometa label again to include the following language in the Precautions section of the label and distributed letters to oncologists and oral surgeons reflecting the same:

> Osteonecrosis of the jaw (ONJ) has been reported in patients with cancer receiving treatment regimens including bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. Many had signs of local infection including osteomyelitis.[4]
>
> A dental examination with appropriate preventative dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g., cancer, chemotherapy, corticosteroids, poor oral hygiene).
>
> While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

Id. ¶ 21. In May 2005, NPC sent a mass-mailing letter to dentists informing recipients of the language change concerning BRONJ in the Zometa label. *Id.* ¶ 42. It read, in part:

> The prescribing information recommends that cancer patients:
>
> - receive a dental examination prior to initiating therapy with intravenous bisphosphonates (Aredia® and Zometa®); and
>
> - avoid invasive dental procedures while receiving bisphosphonate treatment. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. Clinical judgment by the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

Id. ¶ 43.

In 2009, the American Association of Oral and Maxillofacial Surgeons ("AAOMS") issued guidelines regarding BRONJ stating the following:

> Patients may be considered to have BRONJ if all of the following three characteristics are present:
>
> Current or previous treatment with a bisphosphonate.

[4] Osteomyelitis is an inflammation of the bone marrow and adjacent bone. Stedman's Medical Dictionary 1391 (28th ed. 2006).

> Exposed bone in the maxillofacial region that has persisted for more than eight weeks; and
>
> No history of radiation therapy to the jaws.

Id. ¶ 53.

B. Ms. Rowland's Medical History

Ms. Rowland was diagnosed with Stage IV breast cancer in July 2004. *Id.* ¶ 57. By that time, her cancer had spread to her lymph nodes, left hip, and sacrum. *Id.* ¶ 59. Her treating hematologist, Dr. John Waas ("Dr. Waas"), prescribed her Zometa, and Ms. Rowland began treatment with the drug in September 2004. *Id.* ¶¶ 64, 66. As part of routine procedure with chemotherapy patients, Dr. Waas advised her to see a dentist. Deposition of Dr. John Waas ("Waas Dep."), ECF No. 39-55, other portions filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:08-cv-00131, ECF No. 38-26, at 95-96, 115-16.

In April 2005, while on Zometa, Ms. Rowland had one of her teeth extracted. RSOF ¶ 84. She remained on Zometa until October 2005, when Dr. Waas discontinued her treatment. *Id.* ¶ 65. Regarding his decision to stop Zometa, Dr. Waas testified as follows:

> A: I took her off when she complained of pain.
>
> Q: Can you be more specific in relation to pain?
>
> A: In October of 2005 she was complaining of right jaw pain and that is the last – she did not receive any additional Zometa after that particular complaint, the date is in October of 2004 [sic].
>
> Q: You said that you discontinued it because she had jaw pain and at that time were you then aware by October of 2005 of a relationship between bisphosphonate usage and ONJ?
>
> A: Yes.
>
> Q: So would you say that contributed to you taking her off Zometa?
>
> A: Yes.

Waas Dep. at 112-113. Later in his deposition, Dr. Waas explained further:

> A: Because of the jaw pain I stopped it. There's a note in the chart in October saying that I spoke to my nurse, that there's an association between osteonecrosis of the jaw and bisphosphonates and because of the jaw pain, I did not – I discontinued the Zometa.

Id. at 115.

In November 2005, Ms. Rowland saw an oral surgeon, Dr. William Chung ("Dr. Chung"), because of pain in her right jaw. *Id.* ¶ 85. Dr. Chung noted an infection in the area of her April 2005 extraction and recommended an evaluation for a root canal.[5] *Id.* ¶ 87. According to Dr. Chung's deposition testimony, Ms. Rowland never followed up with him about seeing a dentist on his recommendation. Deposition of Dr. William Chung ("Chung Dep."), ECF No. 39-68, other portions filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:08-cv-00131, ECF No. 38-28, at 54-55. In June 2007, Dr. Joseph Cillo ("Dr. Cillo"), an oral surgeon at Allegheny General Hospital in Pittsburgh, Pennsylvania, diagnosed Ms. Rowland with BRONJ. Dr. Cillo Medical Records, originally filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:08-cv-00131, ECF No. 38-34, at 5. Later in June 2007, Ms. Rowland began regular visits with a dentist, Dr. Marc Samuels ("Dr. Samuels"). RSOF ¶ 91. During an October 2007 visit, Dr. Samuels observed smooth exposed bone in the area of Ms. Rowland's extracted tooth. *Id.* ¶ 92. On December 21, 2007, Ms. Rowland filed her suit against NPC in federal district court in the District of Columbia.

In June 2009, Ms. Rowland again saw Dr. Chung. RSOF ¶ 93. He noted exposed bone in the area of her extracted tooth, as Dr. Samuels had. *Id.* Dr. Chung determined that he needed to extract three more of Ms. Rowland's teeth adjacent to her previous extraction and excise her

[5] Throughout his treatment of Ms. Rowland, Dr. Chung prescribed her antibiotics for what he felt was a tooth infection. Deposition of Dr. William Chung, ECF No. 39-68, at 51-52, 70-71, 87-89, 93-96.

right mandible bone. *Id.* He performed those procedures in August 2009. *Id.* ¶ 94. At Ms. Rowland's next appointment, two weeks later, Dr. Chung observed improvement and no exposed bone. *Id.* ¶ 95. However, after another two weeks, Ms. Rowland returned with increased pain in her right jaw. Chung Dep. at 77. A CT scan showed what Dr. Chung suspected was a fracture in Ms. Rowland's jaw, and he performed surgery on her jaw to further explore the problem. *Id.* at 77-79. A pathology report on a piece of bone Dr. Chung removed from Ms. Rowland's jaw indicated that the bone was necrotic (dead). *Id.* at 84. Dr. Chung then attached a reconstruction bar to Ms. Rowland's mandible. RSOF ¶ 97. On December 31, 2009, he removed a small loose piece of dead bone from Ms. Rowland's mouth. Chung Dep. at 87-88. On January 20, 2010, Dr. Chung extracted two more teeth from Ms. Rowland's mouth, along with additional necrotic jawbone. *Id.* at 89-90.

C. Mr. Machen's Medical History

Mr. Machen was diagnosed with Stage IVB Hodgkin's disease in 2006. Defendant's Statement of Material Facts as to Mr. Machen ("MSOF"), ECF No. 35, at ¶ 50. At that time, the disease had metastasized to his bones, including his sacrum, and his lungs. *Id.* ¶ 51. Mr. Machen's treating oncologist, Dr. Robert Finley ("Dr. Finley"), prescribed him Zometa and started treating him with it on July 7, 2006. *Id.* ¶ 58; Deposition of Dr. Robert Finley ("Finley Dep."), ECF No. 35-44, at 74.

By January 2007, Mr. Machen was in remission. MSOF ¶ 63. However, he remained on Zometa until April 2008. *Id.* ¶ 65. Pursuant to a February 27, 2009 checkup, Dr. Finley noted that Mr. Machen had loose teeth in his lower jaw and periodontal disease. *Id.* ¶ 78. On March 2, 2009, Dr. Mark Stein ("Dr. Stein"), a dentist, removed two of Mr. Machen's teeth, a step Dr. Stein believed to be necessary due to bone loss in Mr. Machen's jaw caused by the periodontal

disease. *Id.* ¶ 85; Deposition of Dr. Mark Stein ("Stein Dep."), ECF No. 35-62, at 80-82. On August 27, 2009, Dr. Derek Kelly, another dentist, removed two more of Mr. Machen's teeth. MSOF ¶ 91. Dr. Kelly noted an ongoing abscess in the area of the extracted teeth. Deposition of Dr. Derek Kelly ("Kelly Dep."), ECF No. 35-65, at 172-75. None of those physicians, or any others in the record, ever definitively diagnosed Mr. Machen with ONJ or BRONJ. *See* Finley Dep. at 94; Stein Dep. at 56; Kelly Dep. at 112-13. On July 26, 2010, Mr. Machen filed his suit against NPC in federal district court in the District of Columbia.

D. Mr. Orr's Medical History

Mr. Orr was diagnosed with Stage II multiple myeloma in August 2002. Defendant's Statement of Material Facts as to Mr. Orr ("OSOF"), ECF No. 37, at ¶ 37. At that point, the cancer had metastasized to his bones, including his sacrum, and Mr. Orr had suffered a compression fracture in his spinal cord. *Id.* ¶¶ 37-39. In September 2002, Dr. David Roodman ("Dr. Roodman"), Mr. Orr's initial treating oncologist, prescribed Zometa for him. *Id.* ¶¶ 43-45. Mr. Orr began Zometa treatment on January 6, 2003. *Id.* ¶ 54A. In September 2003, Dr. Roodman referred Mr. Orr to Dr. Michael Carroll ("Dr. Carroll"), another oncologist, for stem cell transplant therapy. Deposition of Dr. David Roodman ("Roodman Dep."), ECF No. 37-41, other portions filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:07-cv-00472, ECF No. 40-12, at 51. Dr. Carroll concurred with Dr. Roodman's conclusion that Zometa was appropriate and kept prescribing it for Mr. Orr. Deposition of Dr. Michael Carroll ("Carroll Dep."), ECF No. 37-42, at 55-56.

On April 21, 2004, Mr. Orr's dentist, Dr. Alan English ("Dr. English"), noticed exposed bone inside his mouth. OSOF ¶ 89A. Mr. Orr was taken off of Zometa on January 27, 2005. *Id.* ¶ 54B. An oral surgeon, Dr. William Hall ("Dr. Hall"), extracted one of Mr. Orr's teeth on

February 15, 2005. *Id.* ¶¶ 91-93. By December 2005, Mr. Orr was in full remission, *id.* ¶ 78, but on December 16, 2005, Dr. Roodman noted that Mr. Orr "has developed [ONJ] while on [IV BP], and developed osteomyelitis." Orr Medical Records, originally filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:07-cv-00472, ECF No. 40-10, at 8. Mr. Orr then reported to Dr. Roodman in October 2006 that his oral issues were "totally resolved." ECF No. 37-67, at 2. On March 15, 2007, Mr. Orr filed his suit against NPC in federal district court in the Southern District of New York.

Over four years after Mr. Orr's first tooth extraction, on September 21, 2009, he returned to Dr. English with a "loose and bleeding" tooth. OSOF ¶ 111. After examination, Dr. English believed this was due to bone loss in Mr. Orr's jaw from his prior cancer treatment and also noted that Mr. Orr had experienced widening of his periodontal ligament. Deposition of Dr. Alan English ("English Dep."), ECF No. 37-55, at 100-01. He referred Mr. Orr to Dr. Hall for further evaluation. OSOF ¶ 111. Dr. Hall concurred with Dr. English's diagnosis and determined that he would have to remove the tooth, warning Mr. Orr of the progression of bone effects from IV BPs. Deposition of Dr. William Hall ("Hall Dep."), ECF No. 37-57, other portions filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:07-cv-00472, ECF No. 40-7, at 86-87. Ultimately, Dr. Hall extracted the tooth on October 16, 2009, later testifying that at that point, "we had no other option." OSOF ¶ 113; Hall Dep. at 89. On the date of the extraction, Mr. Orr signed a consent form that warned of the risks of extraction to a person with ONJ. OSOF ¶ 114. On October 28, 2009, Mr. Orr complained to Dr. Hall of sharp, exposed bone at the site of the extraction. *Id.* ¶ 115. Sadly, Mr. Orr's cancer later returned, and he passed away on October 8, 2012. ECF No. 43. Mrs. Orr, his surviving wife, then entered the case on his behalf. ECF No. 47.

II. LEGAL STANDARD

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett,* 477 U.S. 317, 322–23 (1986). The parties must support their position by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." Fed. R. Civ. P. 56(c)(1)(A).

Once that burden has been met, the non-moving party must set forth "specific facts showing that there is a *genuine issue for trial,*" or the factual record will be taken as presented by the moving party and judgment will be entered as a matter of law. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986) (quoting Fed. R. Civ. P. 56(a), (e)) (emphasis in original). In meeting its burden of proof, the "opponent must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586. The non-moving party "must present affirmative evidence in order to defeat a properly supported motion" and cannot "simply reassert factually unsupported allegations." *Williams v. Borough of West Chester*, 891 F.2d 458, 460 (3d Cir. 1989). If the non-moving party's evidence merely is colorable or lacks sufficient probative force, summary judgment must be granted. *Anderson v. Liberty Lobby, Inc.* 477 U.S. 242, 249-50 (1986).

In other words, summary judgment may be granted only if there exists no genuine issue of material fact that would permit a reasonable jury to find for the nonmoving party. *See id.* at 250. "Where the record taken as a whole could not lead a reasonable trier of fact to find for the

nonmoving party, there is no 'genuine issue for trial.'" *Matsushita*, 475 U.S. at 587; *Huston v. Procter & Gamble Paper Prods. Corp.*, 568 F.3d 100, 104 (3d Cir. 2009).

In reviewing the record evidence, the court draws all reasonable inferences in favor of the non-moving party. *See Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000); *Matsushita*, 475 U.S. at 587–88; *Huston*, 568 F.3d at 104 (citations omitted). It is not the court's role to weigh the disputed evidence and decide which is more probative, or to make credibility determinations. *See Anderson*, 477 U.S. at 255; *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004); *Boyle v. Cnty. of Allegheny*, 139 F.3d 386, 393 (3d Cir. 1998). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson*, 477 U.S. at 247–48. "Where the defendant is the moving party, the initial burden is on the defendant to show that the plaintiff has failed to establish one or more essential elements to his case." *See Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 589 (3d Cir. 2005) (citing *Celotex Corp.*, 477 U.S. at 323–24).

III. DISCUSSION

NPC makes two universal arguments with respect to summary judgment in these cases. First, it asserts that Plaintiffs' non-negligence-based claims (those for strict liability and breach of express and implied warranties) are prohibited by Pennsylvania law.[6] Second, NPC contends that Plaintiffs' negligence claims should also be dismissed because the Zometa warnings were adequate as a matter of law, and under Pennsylvania's learned intermediary doctrine, there is no genuine issue of material fact as to whether the warnings were the proximate cause of their

[6] The Court has jurisdiction over these cases pursuant to 28 U.S.C. § 1332(a), as there is complete diversity between the parties, and the amount in controversy is greater than $75,000. The substantive law of Pennsylvania provides the rules of decision. *Robertson v. Allied Signal, Inc.*, 914 F.2d 360, 378 (3d Cir. 1990) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938)). Pennsylvania law governs all of Plaintiffs' claims. *See Rowland v. Novartis Pharm. Corp.*, 983 F.Supp.2d 615 (W.D. Pa. 2013).

injuries. NPC also makes a separate argument as to Mr. Orr that his claims are barred by the applicable Pennsylvania statute of limitations.

A. Statute of Limitations

Pennsylvania law prescribes a two-year limitations period for personal injury actions. 42 Pa. Cons. Stat. § 5524(2). However, in cases involving "latent injury, and/or instances in which the causal connection between an injury and another's conduct is not apparent, the discovery rule may operate to toll the statute of limitations until the plaintiff discovers, or reasonably should discover, that she has been injured and that her injury has been caused by another party's conduct." *Wilson v. El-Daief*, 964 A.2d 354, 361-62 (Pa. 2009) (citing *Fine v. Checcio*, 870 A.2d 850, 859 (Pa. 2005)). The "salient point giving rise to its application is the inability of the injured, despite the exercise of reasonable diligence, to know that he is injured and by what cause." *Fine*, 870 A.2d at 858. The party relying on the discovery rule bears the burden of proof. *Wilson*, 964 A.2d at 362. To demonstrate reasonable diligence, a plaintiff must show that he exhibited "those qualities of attention, knowledge, intelligence and judgment which society requires of its members for the protection of their own interests and the interests of others." *Cochran v. GAF Corp.*, 666 A.2d 245, 249 (Pa. 1995) (internal citations omitted).

Pennsylvania courts tie commencement of the personal injury limitations period "to actual or constructive knowledge of at least some form of significant harm and of a factual cause linked to another's conduct, without the necessity of notice of the full extent of the injury, the fact of actual negligence, or precise cause." *Wilson*, 964 A.2d at 364. In a case involving a latent injury, the statutory time period "begins to run...at the moment at which the [plaintiff] possessed 'sufficient critical facts to put [him] on notice that a wrong has been committed and that [he needs] to investigate to determine whether [he is] entitled to redress.'" *Debiec v. Cabot*

Corp., 352 F.3d 117, 129 (3d Cir. 2003) (quoting *Zeleznik v. United States*, 770 F.2d 20, 23 (3d Cir. 1985)). But the fact that a plaintiff knows he has been injured in some way

> is not sufficient to trigger such inquiry. One must have some reason to suspect that the injury was caused by a third party to impose a duty to investigate further. Where the injury is one that may result from nontortious conduct, such as a disease, that point may be difficult to discern without resolving factual issues. Subjective differences among persons and the situations in which they find themselves are relevant in making that determination.

Coleman v. Wyeth Parm., Inc., 6 A.3d at 502, 510-11 (Pa. Super. Ct. 2010). Accordingly, only where reasonable minds could not differ as to the determination of the plaintiff's awareness of the injury and its cause may a court rule on a discovery rule tolling question as a matter of law. *Wilson*, 964 A.2d at 362. Factual and credibility determinations regarding the reasonable diligence of a plaintiff are for the finder of fact. *Crouse v. Cyclops Indus.*, 745 A.2d 606, 612 (Pa. 2000). Because a plaintiff's awareness of his injury and its cause is fact intensive, the tolling of the discovery rule is ordinarily a question for the jury. *Wilson*, 964 A.2d at 365-66.

Mr. Orr filed his complaint in the Southern District of New York on March 15, 2007, making March 15, 2005 the relevant tolling date for statute of limitations purposes. An examination of the record reveals a myriad of factual issues surrounding that date and what Mr. Orr knew or should have known about his condition by then. NPC contends that Mr. Orr was sufficiently aware of his injury on February 17, 2005, two days after his first tooth extraction. Dr. Hall testified at his deposition that during the extraction, he removed a piece of Mr. Orr's jawbone for biopsy analysis because had never "seen a necrotic process such as this, and I could not account for what was occurring." Hall Dep. at 54-55. At that point, he had not formed an opinion on what was causing the necrosis, but assumed it was a recurrence of Mr. Orr's cancer. *Id.* at 55. In his February 17, 2005 surgical pathology report, Dr. Hall noted, "most like necrosis from Zometa." ECF No. 37-76 at 2. At the time, Dr. Hall was "somewhat aware" of the risks

involved in performing an extraction on a patient who was on an IV BP medication, but because he did not know that Mr. Orr was receiving Zometa, he did not discuss those risks with him "until later". Hall Dep. at 53-54. Mr. Orr told Dr. Hall at some point after the extraction about his Zometa use due to problems he noticed in his jaw and what he had heard about Zometa causing BRONJ. Deposition of John Orr ("Orr Dep."), ECF No. 37-2, at 182-83. Mr. Orr believed that he was diagnosed with ONJ "probably right after my first extraction," based on the results of the biopsy. Orr Dep. at 181, 200.

Further muddying the waters is the deposition testimony of Dr. Andrew Yeager ("Dr. Yeager"), another of Mr. Orr's treating oncologists. Dr. Yeager saw Mr. Orr on February 28, 2005. OSOF ¶ 120. He noted that "[w]e will also continue to hold on monthly Zometa at this time until we can further evaluate the jaw issue and questionable bone necrosis." ECF No. 37-73 at 4. Dr. Yeager confirmed at his deposition that at the time he did not know exactly what was causing Mr. Orr's jaw problems and was concerned that it could be a return of Mr. Orr's cancer. Deposition of Dr. Andrew Yeager ("Yeager Dep."), ECF No. 37-74, other portions originally filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:07-cv-00472, ECF No. 40-18, at 62-63. He also testified that he was "pretty sure" that during that visit, he had a discussion with Mr. Orr about Zometa as a potential cause of the problems in his jawbone, but neither he nor anyone else had yet diagnosed Mr. Orr with ONJ or BRONJ. *Id.* at 76-77.

A March 28, 2005 pathology report ruled out cancer in Mr. Orr's jaw. ECF No. 37-60. Mr. Orr contends that that date is the earliest he could or should have known about both the nature of his injury and its cause. The record by no means makes that a certainty. What is certain is that the Court cannot conclude as a matter of law that Mr. Orr knew or should have known prior to March 15, 2005, through the exercise of reasonable diligence, that he had BRONJ

caused by Zometa. While a diagnosis is not necessary to toll the limitations period, *Gleason v. Borough of Moosic*, 15 A.3d 479, 485 (Pa. 2011), all that Mr. Orr's doctors did prior to March 15 was consider the possibility that Zometa was causing Mr. Orr's jaw problems and mention that prospect to him. That is not sufficient evidence for the Court to rule as a matter of law that the statute of limitations precludes Mr. Orr's claim. *See Van Eman v. Novartis Pharm. Corp.*, 2013 WL 5603473, at *9-10 (W.D. Pa. Oct. 10, 2013) (declining to hold that the statute of limitations was tolled as a matter of law when the plaintiff's doctors informed him that his condition was potentially BRONJ related to his Aredia and Zometa use but remained uncertain as to whether his initial symptoms were BRONJ or a result of his multiple myeloma). The Court will deny the statute of limitations portion of NPC's Motion.

B. Plaintiffs' Non-Negligence Claims

Ms. Rowland and Mr. Machen assert strict products liability claims against NPC.[7] Under Pennsylvania law, products liability claims may not be brought against a pharmaceutical drug company in strict liability. *See Hahn v. Richter*, 673 A.2d 888, 889-91 (Pa. 1996) (applying RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) to preclude strict liability claims for prescription drugs); *Lance v. Wyeth*, 85 A.3d 434, 451-60 (Pa. 2014) (reaffirming *Hahn*'s bar on strict liability claims but holding that plaintiffs may make claims against pharmaceutical drug companies in negligence for not only manufacturing defects and failure to warn, but also for design defects); *see also Mazur v. Merck & Co., Inc.*, 964 F.2d 1348, 1353-55 (3d Cir. 1992) (holding that under Pennsylvania law, a prescription drug manufacturer's liability is determined through a negligence theory, not strict liability). Accordingly, the Court will grant summary judgment for NPC on those Plaintiffs' strict liability claims.

[7] In her response to NPC's Motion for Summary Judgment, Mrs. Orr withdrew her strict liability and breach of warranty claims. Case No. 2:12-cv-01715-MRH, ECF No. 8-24, at 2.

Ms. Rowland and Mr. Machen also assert claims for breach of express and implied warranties. Courts have interpreted *Hahn* broadly to bar all non-negligence based claims asserted against a manufacturer of prescription drugs. *See Dreisbach v. APP Pharms. LLC*, 2013 WL 5653460, at *2 (M.D. Pa. Oct. 15, 2013); *Salvio v. Amgen*, 810 F.Supp.2d 745, 755-56 (W.D. Pa. 2011); *Leonard v. Taro Pharm. USA, Inc.*, 2010 WL 4961647, at *5 (W.D. Pa. 2010); *Aaron v. Wyeth*, 2010 WL 653984, at *11 (W.D. Pa. 2010); *Kline v. Pfizer, Inc.*, 2008 WL 4787577, at *3 (E.D. Pa. 2008).[8] The Court will therefore grant summary judgment and dismiss those Plaintiffs' breach of warranty claims.

C. Plaintiffs' Negligence Claims

In order to state a claim for negligent failure to warn under Pennsylvania law, a plaintiff must show that (1) the defendant manufacturer owed a duty to the plaintiff; (2) the manufacturer breached that duty; and (3) that breach was the proximate cause of the plaintiff's injuries. *Salvio*,

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[8] In prescription medical device cases, some courts have barred implied warranty claims under *Hahn* but recognized express warranty claims as a viable cause of action without discussing the application of *Hahn* or Section 402A cmt. k of the Second Restatement. *See Dougherty v. C.R. Bard, Inc.*, 2012 WL 2940727, at *8-9 (E.D. Pa. July 18, 2012); *Kee v. Zimmer, Inc.*, 871 F.Supp.2d 405, 410-11 (E.D. Pa. 2012); *Horsmon v. Zimmer Holdings, Inc.*, 2011 WL 5509420, at *3-4 (W.D. Pa. Nov. 10, 2011); *Esposito v. I-Flow Corp.*, 2011 WL 5041374, at *6 (E.D. Pa. Oct. 24, 2011); *Kester v. Zimmer Holdings, Inc.*, 2010 WL 2696467, at *10-11 (W.D. Pa. June 16, 2010); *Parkinson v. Guidant Corp.*, 315 F.Supp.2d 741, 751-52 (W.D. Pa. 2004); *Davenport v. Medtronic, Inc.*, 302 F.Supp.2d 419, 440-41 (E.D. Pa. 2004). Only *Dougherty* has explained why *Hahn* should not preclude express warranty claims for prescription drugs. That court reasoned that a breach of express warranty is more like a breach of contract than a tort and is therefore not applicable to Section 402A cmt. k, which should only apply to warranties implied by law. *Id.* at 8. The *Dougherty* court also read *Hahn* to only apply to failure to warn claims. *Id.* at 9.

Here, Plaintiffs' breach of express warranty claims are grounded in the allegation that NPC failed to properly warn their physicians of the risks posed by Zometa, and in doing so falsely warranted that Zometa was safe for its intended uses. *See Kline*, 2008 WL 4787577 at *3. This directly implicates the language in *Hahn* – "where the adequacy of warnings associated with prescription drugs is *at issue*, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." 673 A.2d at 891 (emphasis added). Additionally, none of the cases excepting breach of express warranty claims from *Hahn*'s bar have dealt with prescription drug products; all have involved a prescription medical device. While prescription drugs and medical devices are often lumped together in this area of the law, *see Kee*, 871 F.Supp.2d at 409 (citing *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006)), the Court declines to apply *Dougherty*'s dicta regarding permissible prescription drug express warranty claims in the face of a uniform body of prescription drug cases reading *Hahn* as barring such claims.

810 F.Supp.2d at 752 (internal citations omitted). The plaintiff must also prove that the manufacturer was at fault. *Id.*

In failure to warn cases involving prescription drugs, Pennsylvania courts apply the learned intermediary doctrine:

> [T]he manufacturer of a prescription drug known to be dangerous for its intended use, has a duty to exercise reasonable care to inform those for whose use the article was supplied of the facts which make the product likely to be dangerous. However, the warnings which are required to be given by the manufacturer must be directed to the physician, not the consumer. This is so because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as it is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug. Thus, in an action against a drug manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate.

Daniel v. Wyeth Pharm., Inc., 15 A.3d 909, 924 (Pa. Super. Ct. 2011) (quoting *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. Ct. 1990)). Thus, by warning the consumer's physician, the manufacturer discharges its duty to the consumer. *Salvio*, 810 F.Supp.2d at 752.

Plaintiffs argue that the duty to warn runs not only to the physician who prescribes the drug in question, but also to other treating doctors such as dentists and oral surgeons. They root this contention in the relevant language of the Restatement (Third) of Torts, which provides that a prescription drug "is not reasonably safe due to inadequate warnings or instructions if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to prescribing and other health-care providers who are in a position to reduce the risks of harm in

accordance with the instructions or warnings." RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(d) (1998). However, while there is currently a great deal of uncertainty as to whether the Pennsylvania Supreme Court has adopted Sections 1 and 2 of the Third Restatement as the controlling analysis for strict products liability claims, *see Sansom v. Crown Equip. Corp.*, 880 F.Supp.2d 648, 653-56 (W.D. Pa. 2012), that court has plainly not yet adopted the Third Restatement's specific test for manufacturer liability for harm caused by defective prescription drugs. *See Lance*, 85 A.3d at 459 n.37 ("[T]his appeal does not present the opportunity for us to consider adoption of an approach or approaches favored by the...Restatement Third...discussion of the degree to which Pennsylvania law may be less restrictive is left for another day.")

Because the Pennsylvania Supreme Court has not issued a controlling decision on the application (or non-application) of the Third Restatement standard of care for negligent failure to warn claims in the prescription drug setting, this Court must predict what rule of law that high court would use.[9] *Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 45-46 (3d Cir. 2009) (internal citation omitted). In doing so, the Court gives "due deference to the decisions of lower Pennsylvania courts." *U.S. Underwriters Ins. Co. v. Liberty Mut. Ins. Co.*, 80 F.3d 90, 93 (internal citation omitted). Those courts have routinely applied Section 388 of the Second Restatement of Torts, which the Pennsylvania Supreme Court previously adopted as the standard of care for prescription drug suppliers. *See Incollingo*, 282 A.2d at 220 n.8; *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984); *Hahn*, 673 A.2d at 890-91 (Pa. 1996); *Daniel*, 15 A.3d

[9] The Pennsylvania Supreme Court recently granted a Petition for Allowance of Appeal in the case of *Tincher v. Omega Flex, Inc.*, 64 A.3d 626 (Pa. 2013), to answer the question of whether the court "should replace the strict liability analysis of Section 402A of the Second Restatement with the analysis of the Third Restatement." That opinion will likely address the nearly impenetrable labyrinth of case law that has taken form since the court's decision in *Phillips v. Cricket Lighters*, 841 A.2d 1000 (Pa. 2003), and seek to determine whether Section 402A of the Second Restatement or Sections 1 and 2 of the Third Restatement: Products Liability are the applicable rule of law as to strict products liability claims. It would seem that the decision in *Tincher* would not directly touch on the specific standards of care for negligence-based failure to warn claims contained in Section 388 of the Second Restatement and Section 6(d) of the Restatement (Third): Products Liability.

at 924 n.13; *Lance v. Wyeth*, 4 A.3d 160, 165 (Pa. Super. Ct. 2010), *rev'd on other grounds*, 85 A.3d 434 (Pa. 2014). Under Section 388, "the supplier has a duty to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." *Hahn*, 673 A.2d at 890.

Pennsylvania courts have held that "the intended 'user' in a case involving a prescription drug or device is, of course, the prescribing physician." *Lineberger v. Wyeth*, 894 A.2d 141, 150 (Pa. Super. Ct. 2006) (quoting *Rosci v. AcroMed, Inc.*, 669 A.2d 959, 968-69 (Pa. Super. Ct. 1995)). The lineage of that "prescribing physician" language can be traced from *Incollingo*, 282 A.2d at 220, to the oft-quoted version of the Pennsylvania learned intermediary doctrine itself, *see Daniel*, 15 A.3d at 924, to the most recent relevant case law, *see Bergstresser v. Bristol-Myers Squibb Co.*, 2013 WL 6230489, at *5 (M.D. Pa. Dec. 2, 2013) (citing *Salvio*, 2012 WL 517446 at *4; *Mazur*, 964 F.2d at 1366; *Fletcher v. Raymond Corp.*, 623 A.2d 845, 848 (Pa. Super. Ct. 1993); *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1154 (Pa. Super. Ct. 1996)). There is no basis for the Court to conclude that Pennsylvania law, in its current state, extends a manufacturer's duty to warn beyond the doctor who prescribed the drug to the plaintiff. The Court will therefore analyze the adequacy of the Zometa warnings in the context of Plaintiffs' prescribing physicians only.

1. Adequacy of the Warnings

NPC contends that it is entitled to summary judgment on the failure to warn claims because the warnings it provided were adequate as a matter of law at the time Plaintiffs were infused with Zometa. In Pennsylvania, the adequacy of a warning is initially a question of law.[10]

[10] NPC also urges the application of a "heeding presumption" under Pennsylvania law. Pursuant to such a presumption, "[w]here a warning is given, the seller may reasonably assume that it will be read and heeded." RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965). In support of the presumption's application to this case, NPC cites *Pavlik v. Lane Ltd./Tobacco Exps. Int'l*, 135 F.3d 876 (3d Cir. 1998), and *Wolfe v. McNeil-PPC, Inc.*, 773

Bergstresser, 2013 WL 6230489 at *5 (internal citations omitted). However, "where fact questions exist...the question of adequacy is one for the jury." *In re Avandia Mktg., Sales Practices and Prods. Liab. Litig.*, 817 F.Supp.2d 535, 545-46 (E.D. Pa. 2011) (internal citations omitted). To find a warning adequate as a matter of law, the label must "accurately and unambiguously convey the scope and nature of the risk, with sufficient specificity given the particular...risk at issue." *Id.* at 546. "Facially accurate statements of fact regarding a particular risk are not adequate as a matter of law where there are disputes over whether the warning was sufficiently explicit and detailed." *Id.* at 546-57 (citing *Incollingo*, 282 A.2d at 212).

Adequacy is determined "based on what a manufacturer knew or should have known about a given risk at the time a patient is prescribed the drug or the cause of action arose, and whether the label warned of that risk." *Id.* at 547. The duty to warn requires a manufacturer to research and investigate risks associated with its product, updating its accompanying warnings as necessary. *Id.* In the prescription drug arena, expert medical testimony is generally required "to determine whether the drug manufacturer's warning to the medical community is adequate because prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect." *Demmler*, 671 A.2d at 1154 (internal citations omitted). Therefore, the general rule is

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F.Supp.2d 561 (E.D. Pa. 2011). In *Pavlik*, the Third Circuit predicted that the Pennsylvania Supreme Court would adopt the heeding presumption as to plaintiffs asserting strict products liability failure to warn claims. 135 F.3d at 882-84. Because there is no strict liability cause of action for failure to warn against prescription drug manufacturers in Pennsylvania, that holding is inapplicable to this case. Further, the *Wolfe* court explicitly stated that the "Pennsylvania Supreme Court has not ruled on whether a heeding presumption applies" to failure to warn cases involving *any* type of drug. 773 F.Supp.2d at 569.

In *Viguers v. Philip Morris USA, Inc.*, the Pennsylvania Superior Court clarified the reach of the heeding presumption in the context of failure to warn claims. 837 A.2d 534, 537-38 (Pa. Super. Ct. 2003), *aff'd*, 881 A.2d 1262 (Pa. 2005). According to that court, the presumption has only been authorized in Pennsylvania in cases involving workplace exposure to asbestos. *Id.* at 537. The court held that the presumption did not apply in the context of a plaintiff's voluntary choice to smoke tobacco, as the strong public policy rationale for the presumption where a plaintiff is forced by employment to be exposed to the product allegedly causing harm was not present there. *Id.* at 538. Without providing an opinion, the Pennsylvania Supreme Court affirmed *Viguers*. 881 A.2d 1262. As the facts of this case do not invoke or favorably implicate the public policy discussed in *Viguers*, the Court concludes that the heeding presumption does not apply to this case.

that "adequacy is ordinarily a question for the jury and must be determined based on both risks disclosed and the manufacturer's actual or constructive knowledge at the time the injury occurred." *In re Avandia*, 817 F.Supp.2d at 548.

Nothing in the record compels the Court to deviate from that general rule. The adequacy of NPC's warnings for the varied time frames during which these Plaintiffs were prescribed and infused with Zometa is the crucial hotly contested issue in these cases, and the factual landscape is littered with disputes as to timing and what NPC knew or should have known about BRONJ. The parties have enlisted armies of expert witnesses to testify as to such matters. *See Rowland v. Novartis Pharm. Corp.*, 2014 WL 1316351 (W.D. Pa. Mar. 31, 2014). Further, the MDL court previously ruled that genuine issues of material fact exist as to the adequacy of the Zometa warnings. *See In re Aredia and Zometa Prods. Liab. Litig.*, 2011 WL 2182824, at *5 (M.D. Tenn. June 3, 2011) (referencing M.D. Tenn., MDL No. 3:06-MD-1760, ECF Nos. 2766 and 2767). Under the law of the case doctrine, a transferee court may not depart from the previously entered order of the MDL court except in extraordinary circumstances. *In re Pharmacy Benefit Mgrs. Antitrust Litig.*, 582 F.3d 432, 439 (3d Cir. 2009) (internal citations omitted). NPC has presented no such circumstances. The adequacy of the Zometa warnings is a properly a question of fact for the jury to consider.

2. Proximate Cause

NPC next asserts that the Plaintiffs cannot demonstrate any genuine issue of fact as to whether the Zometa warnings were the proximate cause of their injuries. According to NPC, a different warning would not have prevented Plaintiffs' injuries, because the record shows that their prescribing physicians would still have prescribed and treated them with Zometa, even with full knowledge of the drug's association with BRONJ.

Within the vast swath of Zometa cases nationwide, courts applying various state law versions of the learned intermediary doctrine have split on whether such a record in a given case is sufficient to grant summary judgment on a failure to warn claim. According to some courts, such evidence essentially forecloses any genuine issue of fact as to whether NPC's failure to warn was the proximate cause of a plaintiff's injury.[11] Others have held that it is not a dispositive question for purposes of summary judgment, and concluded that evidence of a plaintiff's prescribing doctor making changes to his treatment and prescription procedures in response to increased awareness of the BRONJ risk, in some cases even where that doctor would still prescribe the drug, creates a triable question of fact as to proximate cause.[12]

Pennsylvania courts have taken a case-by-case approach. In *Demmler v. SmithKline Beecham Corp.*, the Pennsylvania Superior Court laid out the test:

> In the duty to warn context, assuming that plaintiffs have established both duty and a failure to warn, plaintiffs must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided.

671 A.2d 1151, 1155 (Pa. Super. Ct. 1996) (quoting *Mazur v. Merck & Co., Inc.*, 742 F.Supp. 239, 262 (E.D. Pa. 1990), *aff'd on other grounds*, 964 F.2d 1348 (3d Cir. 1992)). The *Demmler* court granted summary judgment on a failure to warn claim because the plaintiff presented no "proof that a more thorough or more explicit warning would have prevented [her] use of [the

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[11] *See Ingram v. Novartis Pharm. Corp.*, 888 F.Supp.2d 1241, 1245-47 (W.D. Okla. 2012); *Payne v. Novartis Pharm. Corp.*, 967 F.Supp.2d 1223, 1230-31 (E.D. Tenn. 2013); *Luttrell v. Novartis Pharm. Corp.*, 894 F. Supp. 2d 1324, 1345-46 (E.D. Wash. 2012); *D'Agnese v. Novartis Pharm. Corp.*, 952 F.Supp.2d 880, 891-93 (D. Ariz. 2013); *Parkinson v. Novartis Pharm. Corp.*, 2014 WL 1098123, at *7-10 (D. Or. Mar. 20, 2014); *Garrison v. Novartis Pharm. Corp.*, 2014 WL 2968510, at *6-8 (M.D. Ala. July 2, 2014).

[12] *See Georges v. Novartis Pharm. Corp.*, 2012 WL 9083365, at *5-6 (C.D. Cal. Nov. 2, 2012); *Hill v. Novartis Pharm. Corp.*, 2012 WL 6004161, at *4 (E.D. Cal. Nov. 30, 2012); *Rutz v. Novartis Pharm. Corp.*, 2012 WL 6569361, at *7-8 (S.D. Ill. Dec. 17, 2012); *Davids v. Novartis Pharm. Corp.*, 857 F.Supp.2d 267, 288-89 (E.D.N.Y. 2012); *Chiles v. Novartis Pharm. Corp.*, 2013 WL 5769903, at *7 (M.D. Fla. Feb. 7, 2013); *Guenther v. Novartis Pharm. Corp.*, 2013 WL 1498162, at *2 (M.D. Fla. May 10, 2013); *Stanley v. Novartis Pharm. Corp.*, 2014 WL 1316217, at *11-12 (C.D. Cal. Apr. 2, 2014); *Bee v. Novartis Pharm. Corp.*, 2014 WL 1855632, at *18-23 (E.D.N.Y. May 9, 2014); *Kruszka v. Novartis Pharm. Corp.*, 2014 WL 1878771, at *15-16 (D. Minn. May 12, 2014); *Kirchman v. Novartis Pharm. Corp.*, 2014 WL 2158519, at *4-6 (M.D. Fla. May 23, 2014).

drug]...the record is devoid of any evidence that a different warning would have altered [her] use of [the drug] in accordance with [her doctor's] instructions." *Id.* at 1155-56. The Superior Court also granted summary judgment in *Lineberger v. Wyeth*, where the court found the record to be "devoid of evidence to support [plaintiff's] argument that a different warning would have altered [her doctor's] prescribing methods *vis-à-vis* [plaintiff]." 894 A.2d at 150-51. The court held that summary judgment was warranted because the plaintiff's physician testified that a different warning would not have changed his decision to prescribe the drug in question. *Id.*

Two other recent Pennsylvania Superior Court decisions provide examples of sufficient record evidence to establish a triable issue as to proximate cause. In *Simon v. Wyeth Pharm., Inc.*, the court held that a trial court erred in granting judgment notwithstanding verdict ("JNOV") for failure to demonstrate proximate cause. 989 A.2d 356, 376 (Pa. Super. Ct. 2009). The plaintiff's prescribing physician testified that, if he had current information about the increased risk of developing breast cancer posed by the drug in question, he would have had "no qualms" about prescribing it to the plaintiff, but would have warned her about that risk, as he had changed his standard practices to include such warnings in his discussions with patients about the drug. *Id.* at 374-75. Additionally, the plaintiff testified that if she had been warned of that risk, she would not have taken the drug. *Id.* at 375. On that basis, the court held that the plaintiff had shown proximate cause, as "a more complete labeling of [the drug] would have altered the prescribing practices of the physicians and [plaintiff's] use of the drug." *Id.*

On similar facts, in *Daniel v. Wyeth Pharm., Inc.*, the Superior Court held that a trial court did not err in denying JNOV to a drug company on a failure to warn claim as to proximate cause. 15 A.3d 909, 925 (Pa. Super. Ct. 2011). In that case, the plaintiff's prescribing doctor testified that, had he been provided with a different warning about the risk of breast cancer

inherent to the drug in question, he would have "passed this information along to [the plaintiff] and emphasized it during their discussions regarding the risks associated with taking the drug." *Id.* at 924-25. The plaintiff claimed that had she been warned about the possibility of developing breast cancer, she would not have taken the drug. *Id.* at 925.

Because the proximate cause inquiry under the learned intermediary doctrine is plainly and centrally fact-intensive, the Court will analyze the relevant facts of each case here and determine whether each Plaintiff has demonstrated the existence of a genuine issue of material fact as to whether NPC's Zometa warnings were the proximate cause of their injuries.

a. Ms. Rowland

Dr. Waas prescribed Zometa to Ms. Rowland. Waas Dep. at 37. He testified at his deposition that he could not recall whether he was aware of an association between IV BPs and ONJ when he prescribed Zometa to Ms. Rowland in September 2004. *Id.* at 45, 93, 113. He noted such a relationship in Ms. Rowland's chart for the first time in October 2005. *Id.* at 45. At his deposition, Dr. Waas testified about the effect knowledge of the risk of BRONJ has had on his Zometa prescribing practices:

> A: ...[W]hen I recall the concern that physicians have about complications due to medication and osteonecrosis was one of those that became noticed and from that point forward, it was a very big concern with every patient I placed on Zometa. I still use Zometa, it does not prevent me from using it, but it is a concern.

Id. at 46.

> Q: Do you use Zometa and Aredia in the same way that you did in 2004?
>
> A: Yes.
>
> Q: Do you give the same warnings regarding Zometa and Aredia in the same way you did in 2004?
>
> A: I would have to say no.

Q: And in what way is your warning today different than it was in 2004?

A: Again not recalling exactly what it was then, there's a greater amount of time spent on describing the risk of osteonecrosis.

Id. at 111.

Dr. Waas also testified about his decision to prescribe Zometa to Ms. Rowland specifically:

Q: So then thinking back to 2004, if you had been aware at that time, would you have warned Ms. Rowland of any type of relationship or precaution to avoid that relationship or trigger between ONJ and bisphosphonates?

A: I probably would have, but I can't say with certainty.

Q: ...[T]hinking back to September of 2004, if you had known of the relationship between bisphosphonates and ONJ, would that have changed your risk benefit analysis before prescribing to Ms. Rowland?

A: No.

Id. at 95.

Q: So if you had known [the relationship between IV BPs and ONJ] in September of 2004, would that also have changed either the fact that you prescribed her Zometa or the way you prescribed her Zometa?

A: No, in that I felt she needed the Zometa because of the risk of skeletal events.

Q: I guess what I'm having trouble with is that it seems like in October of 2005 you discontinued Zometa because she had jaw pain and you knew of the relationship between bisphosphonate usage and ONJ, and my question was if you had known that in September of 2004, would that have changed your decision to prescribe Zometa?

A: No.

Id. at 113-15.

It is plain from the record that Dr. Waas, if cognizant of the risk of BRONJ, would still have prescribed Zometa to Ms. Rowland. However, he also indicated that he extensively discusses that risk as a "very big concern" with his patients, something he did not do with Ms.

Rowland because of his lack of knowledge at the time. Further, at her deposition, Ms. Rowland testified that if apprised of the risk of BRONJ, she would not have taken Zometa. Deposition of Karen Rowland, originally filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:08-cv-00131, ECF No. 38-27, at 127-28. In those respects, the record bears significant similarity to *Simon* and *Daniel*, where a triable issue as to proximate cause was established. The Court concludes that a genuine issue of fact exists as to proximate cause because if given a different warning, Dr. Waas would likely have advised Ms. Rowland of the risk of BRONJ, and she could have refused to take the drug.[13] NPC's Motion for Summary Judgment as to Ms. Rowland's negligent failure to warn claim will therefore be denied.

b. Mr. Machen

In a failure to warn case, "before a plaintiff can prove that a non-disclosed risk would have altered his physician's decision to prescribe a drug, the plaintiff must demonstrate that he/she suffered from the precise injury that the manufacturer allegedly failed to disclose." *Cochran v. Wyeth, Inc.*, 3 A.3d 673, 681 (Pa. Super. Ct. 2010). NPC argues that Mr. Machen cannot demonstrate proximate cause because he never developed ONJ at all, pointing to the facts that none of Mr. Machen's treating physicians ever diagnosed him with ONJ or BRONJ, and that he never displayed some of the telltale signs of BRONJ as identified by the AAOMS diagnosis guidelines.

[13] In arguing that Dr. Waas' testimony that he would still have prescribed Zometa is enough to grant summary judgment, NPC cites to *Cochran v. Wyeth*, 3 A.3d 673, 679 (Pa. Super. Ct. 2010), where the Pennsylvania Superior Court, citing *Demmler*, wrote, "[T]o succeed in a failure to warn claim, a plaintiff must establish that had the physician been aware of the non-disclosed risk, the physician never would have prescribed the drug." That is not the legal standard articulated in *Demmler*. According to *Demmler*, a plaintiff may establish proximate cause for failure to warn by showing that had the defendant given a proper warning to the plaintiff's prescribing doctor, that doctor would have altered his prescribing *behavior*, not necessarily his decision to prescribe, and the injury would have been avoided. 671 A.2d at 1155. As *Simon* and *Daniel* make plain, a genuine issue of fact as to proximate cause is properly established where a plaintiff shows that the prescribing physician, with knowledge of the risk at issue, would have warned the plaintiff (or warned the plaintiff differently) about that risk, and the plaintiff, so warned, may not have taken the drug.

However, Dr. Kelly conducted a differential diagnosis of Mr. Machen in August 2009 and concluded that Mr. Machen's condition was most likely BRONJ. Kelly Dep at 200-02. Additionally, Mr. Machen's causation expert, Dr. Talib Najjar, testified to a reasonable degree of medical certainty, based on a differential diagnosis he conducted, that Mr. Machen developed BRONJ as a result of his Zometa treatment. Deposition of Dr. Talib Najjar ("Najjar Dep."), ECF No. 35-57, other portions filed in M.D. Tenn., MDL No. 3:06-MD-1760, Case No. 3:10-cv-00830, ECF No. 42-25, at 29-30. Dr. Najjar admitted that Mr. Machen did not display necrotic or exposed jaw bone, both of which are characteristics required by the AAOMS guidelines for a diagnosis of Stage I BRONJ. *Id.* at 44-45, 148-49. But, he also testified that he believed Mr. Machen suffered from a "BRONJ-like lesion" or bony defect in his jaw that was Stage I BRONJ pursuant to his own criteria. Najjar Dep. at 47-48, 60-61, 149. Mr. Machen argues that Dr. Najjar's diagnosis is akin to "Stage 0" BRONJ, which the AAOMS defined in a 2009 position paper as found in "patients with no clinical evidence of necrotic bone, but present with non-specific symptoms or clinical and radiographic findings." ECF No. 37-46, at 12.

The Court has previously concluded that Dr. Kelly may testify at a trial about his treatment and independent diagnosis of Mr. Machen, and that Dr. Najjar is qualified to testify as to causation of Mr. Machen's injuries. *See Rowland*, 2014 WL 1316351, at *7-9. Their expert medical opinions create a genuine issue of fact as to whether Mr. Machen actually had BRONJ.

NPC further argues that even if Mr. Machen had BRONJ, he has no way of establishing that a different warning would have prevented his injury. At his deposition, Dr. Finley testified that he could not recall whether he had heard about a possible relationship between Zometa and ONJ when he began Mr. Machen on the drug in July 2006. Finley Dep. at 75-76. He also could not remember providing Mr. Machen with any information about ONJ or having any discussion

with him about a pre-treatment dental exam. Finley Dep. at 79-81. However, the record shows that on the day he first administered Zometa to Mr. Machen, Dr. Finley signed a standardized Zometa administration form produced by his office that stated:

> Additional information: Osteonecrosis of the jaw has been reported in patients with cancer who were receiving chemotherapy, corticosteroids, and chronic bisphosphonate therapy; symptoms included non-healing extraction socket or exposed jawbone. Dental exams and preventative therapy should be performed prior to placing patients with risk factors (e.g., chemotherapy, corticosteroids, poor oral hygiene) on chronic bisphosphonate therapy. Invasive dental procedures should be avoided during treatment.

MSOF ¶¶ 67-68. Dr. Finley testified that the proper standard of care would have been to give Mr. Machen the form, but was not sure if he had done so. Finley Dep. at 81.

As to his current Zometa prescribing practices, Dr. Finley testified:

> Q: What warnings do you give to patients today in relation to ONJ before prescribing the drug?
>
> A: We have that -- the consent form. We go through the discussion with them and we will recommend that they have a dental exam and we have a dental clearance form that we are using currently.
>
> Q: Can you explain the dental clearance form?
>
> A: Yes. It is a form in which the patient -- we ask the patient to go see a dentist and have a dental exam and have the dentist or the oral health professional give an okay for them to receive bisphosphonates.
>
> Q: Do you know when you started doing that?
>
> A: Within the last one to two years.

Id. at 121-22. Dr. Finley admitted that at least one of his patients has since refused treatment with Aredia or Zometa due to learning about the risk of BRONJ through news reports. *Id.* at 55.

NPC suggests that the "discussion" and dental clearance form Dr. Finley now gives Zometa patients are irrelevant to Mr. Machen's case because neither would have prevented any injury to him. Dr. Najjar admitted at his deposition that Mr. Machen's alleged BRONJ was not

related to a tooth extraction. Najjar Dep. at 43-44. He also could not say that a pre-Zometa dental examination would have prevented BRONJ for Mr. Machen. *Id.* at 29. Before his August 27, 2009 tooth extraction by Dr. Kelly, Mr. Machen signed a consent form expressly warning of the risks of oral surgery for patients who had taken IV BPs. MSOF ¶¶ 93-94. There is no evidence that he signed a similar form attendant to Dr. Stein's March 2, 2009 extraction. However, both dentists testified that the extractions were necessary because the teeth had become infected and had to come out. Stein Dep. at 81-82; Kelly Dep. at 157.

On one hand, Dr. Finley has changed his prescribing behavior to discuss the risk of BRONJ with patients, and ensures that they receive the go-ahead from a dentist before he administers the drug to them. On the other hand, Pennsylvania case law requires a plaintiff to show that with a different warning, the prescribing doctor would have changed his prescribing practices, *and* the plaintiff's injury would have been avoided. Mr. Machen has not demonstrated how, if Dr. Finley had discussed the risk of BRONJ with him[14] and had him undergo a dental examination, he would have avoided injury. Nothing in the record indicates that Mr. Machen would have (or even may have) refused to take Zometa if he had been advised of the BRONJ risk. His tooth extractions were necessary due to other health concerns, and his own expert witness conceded that his alleged BRONJ was unrelated to either of his extraction procedures. Therefore, a dental examination would not have turned up anything prohibitive to Mr. Machen undergoing Zometa treatment. The Court will consequently grant summary judgment and dismiss Mr. Machen's failure to warn claim. The Court will also dismiss Mrs. Machen's loss of consortium claim, as her spouse's underlying negligence claim no longer persists. *See Craig v.*

[14] In the Court's view, evidence of other patients of Dr. Finley refusing to take Zometa due to information from the media, *supra* p. 28, is far less relevant than evidence of other patients refusing it because of Dr. Finley's warnings, which is not in the record. No issue of triable fact is created as to the adequacy of the warnings as a result of the effects of news reports.

Franklin Mills Assoc., L.P., 555 F.Supp.2d 547, 555 (E.D. Pa. 2008), *aff'd sub nom.*, 350 F. App'x 714 (3d Cir. Oct. 30, 2009). Because none of the Machens' claims against NPC survive summary judgment, the Court will dismiss their case.

c. Mr. Orr

Dr. Roodman initially prescribed Zometa to Mr. Orr. OSOF ¶¶ 43-45. He was not aware of the risk of developing BRONJ from IV BPs at that time. *Id.* ¶ 44. At his deposition, he maintained that a different warning about the risk of BRONJ would not have changed his decision to prescribe it to Mr. Orr, stating, "I would have counseled him about the risk and benefits of the treatment and let him make an informed decision." Roodman Dep. at 53-54. He also testified about changes in his Zometa prescribing practices since learning of that risk:

> Q: Have you changed your prescribing habits at all based on reports of ONJ occurring in patients taking Zometa?
>
> A: I've changed the duration of treatment.
>
> Q: At some point since 2003, have you started explaining to patients the potential risk of ONJ?
>
> A: Yes, and have them get dental evaluations prior to starting therapy.

Roodman Dep. at 48, 51.

Dr. Carroll concurred in Dr. Roodman's Zometa recommendation and similarly testified that he would still prescribe Zometa to Mr. Orr despite his knowledge of the risk of BRONJ. Carroll Dep. at 56, 58-59. But, like Dr. Roodman, he has since begun to routinely explain to patients the risk of BRONJ posed by Zometa. *Id.* at 58. Mr. Orr testified at his deposition that if he had been told there was any more than a three (3) percent chance that he would develop BRONJ from taking Zometa, he would not have agreed to take the drug. Orr Dep. at 169-70. The incidence rate of BRONJ in IV BP patients is a contested issue in this case, and the Court

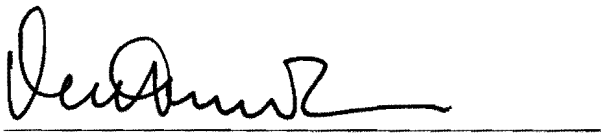
has approved the testimony of several of Plaintiffs' expert witnesses on that topic for trial. *See Rowland*, 2014 WL 1316351 at *6-8. As it is not the Court's province to make credibility determinations based on the summary judgment record, Mr. Orr's deposition testimony, taken in conjunction with that of the physicians who prescribed him Zometa, creates a genuine issue of material fact regarding proximate causation. Although Mr. Orr's doctors would still have prescribed Zometa to him, they also would have disclosed the risk of BRONJ and its effects. Those warnings may have induced Mr. Orr to refuse to take the drug, which in turn would have prevented his injury. The Court will therefore deny summary judgment on Mr. Orr's failure to warn claim.

IV. CONCLUSION

For the reasons stated in this Opinion, the Court rules as follows on Defendant's Motions for Summary Judgment:

1. The Motions as to Plaintiffs' claims for strict liability, breach of express warranty, and breach of implied warranty are granted, and those claims are dismissed;
2. The Motion as to Ms. Rowland's claim for negligent failure to warn is denied;
3. The Motion as to Mr. Machen's claim for negligent failure to warn is granted, and such claim is dismissed; Mrs. Machen's attendant claim for loss of consortium is also dismissed; and the Machens' case is accordingly dismissed; and
4. The Motion as to Mrs. Orr's claim for negligent failure to warn is denied.

An appropriate Order will follow.



Mark R. Hornak
United States District Judge

Dated: July 28, 2014
cc: All counsel of record