UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WASHINGTON

DUANE E. LUTTRELL, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendants.	NO: 07-CV-3015-TOR ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND MOTION TO EXCLUDE CAUSATION TESTIMONY

BEFORE THE COURT is Defendant's Motion for Summary Judgment (ECF No. 44-55) and Defendant's Motion to Exclude Causation Testimony of Plaintiff's Experts (ECF No. 43-53). These matters were heard with oral argument on August 10, 2012. John J. Beins and David P. Abeyta appeared on behalf of the Plaintiff. Donald R. McMinn and James B. King appeared on behalf of Defendant. The Court has reviewed the relevant pleadings and supporting materials, and is fully informed.

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BACKGROUND

In 2007, Duane Luttrell ("Luttrell") filed his original Complaint in the Eastern District of Washington alleging that Aredia® and Zometa®, drugs manufactured by Novartis Pharmaceuticals Corp. ("Novartis"), caused him to develop osteonecrosis of the jaw. ECF No. 1. The case was transferred to the Middle District of Tennessee as part of a Multi-District Litigation ("MDL"). In January of 2012, the MDL court held that the purposes of the MDL were accomplished, and remanded the pending motions back to this Court for decision. ECF No. 6. Presently before the Court is Defendant's Motion for Summary Judgment (ECF No. 44-55) and Defendant's Motion to Exclude Causation Testimony by Plaintiff's Experts (ECF No. 43-53).

Luttrell's Complaint alleged five causes of action; 1) strict liability, 2) negligent manufacture, 3) negligent failure to warn, 4) beach of express warranty, and 5) breach of implied warranty. ECF No. 1. Luttrell now concedes that his manufacturing defect and his express warranty claims should be dismissed. ECF No. 46-91 at 1. Additionally, Luttrell has not contested that his implied warranty claim should be dismissed. Luttrell has two remaining claims: "strict liability" and

failure to warn.[1]

FACTS

Osteonecrosis of the jaw ("ONJ") is a "dead jaw bone." Defendant's Statement of Undisputed Facts in Support of Summary Judgment ("Def. SUF") ¶ 1. Bisphosphonate therapy has been associated with ONJ, and the American Association of Oral and Maxillofacial Surgeons ("AAOMS") has created a diagnosis of bisphosphonate-related ONJ ("BRONJ") for patients with (1) current or previous treatment with bisphosphonates, (2) with exposed bone in the maxillofacial region that has lasted for more than 8 weeks, and (3) no history of radiation therapy to the jaw. Def. SUF ¶ 2.[2] Novartis repeatedly contends, although it is disputed by Luttrell, that other conditions or therapies can cause or

[1] Under the WPLA there is no separate claim for "strict liability." As discussed in Section II.B infra, the WPLA created a single cause of action for product-related harms by proving that the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided." Wash. Rev. Code § 7.72.030(1). Thus, Luttrell's only remaining claim is the failure to warn.

[2] This definition can be found in Luttrell's reply to Novartis' SUF ¶ 2.

contribute to ONJ, including, but not limited to: osteomyelitis (a bacterial or fungal infection of the bone), chemotherapy, corticosteroid use, cancer, trauma, radiation therapy, diabetes, and heavy smoking. *Id*.

In the mid 1990's, the United States Food and Drug Administration ("FDA") approved Aredia®, an intravenous bisphosphonate drug manufactured by Novartis, to treat multiple myeloma and hypercalcemia of malignancy. Def. SUF ¶ 12-13. Aredia® remains on the market today as an FDA approved drug. Def. SUF ¶ 14. In February of 2002, the FDA approved Zometa®, another intravenous bisphosphonate drug manufactured by Novartis and used for treating multiple myeloma. Def. SUF ¶ 17-18. According to Dr. Brady, Luttrell's prescribing physician, these drugs are prescribed to "reduce the possibility or eliminate the possibility of so-called skeletal related event, particularly in multiple myeloma patients." Def. SUF ¶ 23 (citing Brady dep. at 17) (Luttrell objects to the statement that Zometa® prolongs remission).

In April 2001, the FDA approved pamidronate, a generic version of Aredia® that is not manufactured by Novartis. Def. SUF ¶ 15. The introduction of the generic version of pamidronate dropped Novartis' market share from 98% in 2001 to 1% in 2005 and 2006 when Luttrell received the drug. Def. SUF ¶ 16.

It is disputed as to exactly when and how Novartis discovered the association of bisphosphonate drugs and ONJ. See Def. SUF and Pl. Responses

¶ 24-30. It is undisputed that Novartis sent "Dear Doctor" letters to hematologists, urologists, oral surgeons, and oncologists informing prescribers of the change in the label in September 2004 that included the following language:

> Osteonecrosis of the jaw ("ONJ") has been reported in patients with cancer receiving treatment regimens including bisphosphonates…A dental examination with appropriate preventative dentistry should be considered prior to treatment with bisphosphonates for patients with concomitant risk factors (e.g. cancer, chemotherapy, corticosteroids, poor oral hygiene). While on treatment, those patients should avoid invasive dental procedures if possible.

Def. SUF ¶ 33-34 (Luttrell disputes that the letter was actually received by his treating physician). In addition, Novartis sent a "Dear Dentist" letter to oral surgeons, dentists, specialists in periodontics and prosthodontics in May of 2005 that included the following language in the Precautions section:

> 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. A dental examination with appropriate preventative dentistry should be considered prior to treatment with bisphosphonates for patients with concomitant risk factors (e.g. cancer, chemotherapy, corticosteroids, poor oral hygiene).
>
> While on treatment, those 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 patients based on individual benefit/risk assessment.

Def. SUF ¶ 35-36 (Luttrell disputes that label was received by him or his physician). Novartis also included language in its Post-Marketing Experience section 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 (See PRECAUTIONS).

Id.[3]

On June 21, 2005, Duane Luttrell was diagnosed with multiple myeloma by his oncologist Dr. Albert Brady ("Dr. Brady"), and the next day he received his first dose of Zometa®. Def. SUF ¶ 40. After this dose, Luttrell experienced "fatigue, fevers, chills, and anthralgias." ECF No. 46-91 at 6 (citing Brady dep. at 20). Dr. Brady noted in Luttrell's medical records that "[w]e talked about Zometa® and that we would try Aredia®. If that works [i.e. doesn't give him flu like symptoms], great. If it does not work we will just can this whole

[3] In its response to the SUF ¶ 36, Luttrell contends that this warning is false and misleading to blame other risk factors and that the warning was buried in the label and difficult to find in the packaging.

bisphosphonate thing." ECF No. 46-91 at 7 (citing Brady dep. at 24-25). Luttrell did not experience flu like symptoms so Dr. Brady continued him on Aredia®, which he received monthly through May 2006. *Id*. Novartis disputes that Luttrell actually received Aredia® and not the generic pamidronate.[4] Def. SUF ¶ 49. Novartis has submitted plaintiff's oncologist's purchasing records that show only generic pamidronate was purchased from December 8, 2005 through November 17, 2009. ECF No. 73-4. That accounts for five of the eleven doses Luttrell received before he stopped taking the drug, temporarily.

On July 20, 2005, one day before he had his first dose of Aredia®, Luttrell was referred to an oral surgeon to have a tooth extracted. Def. SUF ¶ 46. Dr. Brady called Luttrell's dentist and asked that he take a "panorex" of Luttrell's jaw to monitor for any changes. Def. SUF ¶ 47 (Luttrell disputes that bisphosphonates were mentioned in this phone call). Luttrell complained of sores in his mouth and had further dental work performed in May of 2006, including grinding down several of Luttrell's teeth and correcting Luttrell's hyperocclusion. Def. SUF ¶ 52-56.

[4] The Court will continue to refer to "Aredia®" as the drug administered to Luttrell. However, the Court recognizes the dispute as to whether Luttrell was given Aredia® or generic pamidronate, and will address that argument below.

In June of 2006, after complaining of pain in his jaw, Luttrell was sent to Dr. Sean Cleary, a radiation oncologist. ECF No. 46-91 at 7 (citing Brady dep. at 27). Dr. Clearly found that the cancer had not spread to the jaw; instead, he found Luttrell's jaw pain was "most consistent with osteonecrosis, secondary to bisphosphonate therapy." ECF No. 46-91 at 7 (citing Brady dep. at 28). At this time Dr. Brady took Luttrell off Aredia®, however, after this lawsuit was filed, Luttrell resumed Aredia® or pamidronate treatments intermittently through November of 2009. Def. SUF ¶ 58-61. The instant lawsuit was filed in March of 2007. Def. SUF ¶ 59.

Over the entire course of these treatments, Dr. Brady continually wrote a diagnosis of BRONJ in Luttrell's medical records.[5] ECF No. 46-91 at 8 (citing Brady dep. at 31, 33, 37, 54). Dr. Brady also sent Luttrell to an oral surgeon, Dr.

[5] Luttrell argues that Dr. Brady attempted to change his diagnosis to include other risk factors such as "malignancy, poor oral hygiene, steroid therapy, and chemotherapy" and points out that Dr. Brady never identified these risk factors as possible causes of Luttrell's ONJ in the medical records. ECF No. 46-91 at 8. Luttrell also maintains that Dr. Brady is not an impartial witness because he has been employed since 2010 by Novartis as an expert witness in other cases. ECF No. 46-91 at 14, n.7.

Tew, who also diagnosed Luttrell with BRONJ. ECF No. 46-91 at 7 (citing Brady dep. at 29-30). Dr. Tew, in turn, sent biopsied bone to Dr. Oda, an oral pathologist at the University of Washington, who noted that "the histology of the fragment was consistent with bisphosphonate-induced osteonecrosis of the mandibular torus." Def. SUF ¶ 66. As of Dr. Brady's final entry in Luttrell's medical records in February of 2009, Luttrell's jaw had re-epitheliazed (his skin had healed). Def. SUF ¶ 66.

DISCUSSION

I. Motion to Exclude Expert Testimony on Causation

Expert witness testimony is governed by Federal Rule of Evidence 702, which provides:

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

Fed. R. Evid. 702. Rule 702 should be applied consistent with the "liberal thrust" of the Federal Rules and their "general approach of relaxing the traditional barriers to 'opinion testimony'." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588 (1993) (*citing Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988)). The proponent of expert testimony must establish the admissibility of expert testimony

by a preponderance of the evidence. *Henricksen v. ConocoPhillips Co.*, 605 F. Supp.2d 1142, 1154 (E.D. WA 200 9).

The trial court is accorded wide discretion when acting as gatekeepers for the admissibility of expert testimony. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 151-52 (1999). As an initial matter, the court must determine if a witness has the required expertise, whether it be "knowledge, skill, experience, training, or education" under Rule 702(a). Next, the court turns to the content of the expert's proffered testimony to assess whether the proffered testimony is both relevant and reliable. *Henricksen*, 605 F. Supp. at 1153 (*citing Daubert*, 509 U.S. at 589). In order to determine whether the testimony is admissible, the court must analyze "whether the reasoning or methodology underlying the testimony is scientifically valid, and [] whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592.

A. Testimony of Treating Physicians

Pursuant to Rule 702, treating physicians must be sufficiently qualified to testify as an expert, and the court must determine whether the methodology underlying the testimony is scientifically reliable, and whether it is relevant to the facts of this case. *Daubert*, 509 U.S. at 592. Novartis contends that Luttrell has not met his burden to show that several of the treating physicians have the requisite

expertise to testify as experts under the *Daubert* standard.[6] ECF No. 44-1 at 8. In addition, Novartis argues that none of Luttrell's treating physicians have a known causation opinion, and therefore any proffered causation testimony is inadmissible. ECF No. 44-1 at 7-15.

Luttrell maintains that courts have found a treating doctor's opinion on causation admissible because it is an "integral part of treating a patient." *Fielden v. CSX Transp., Inc.*, 482 F.3d 866, 870-71 (6th Cir. 2007) (distinguishing testimony regarding causation that pertains to the treatment of the patient, from causation testimony prepared in anticipation of litigation). The Ninth Circuit recently joined other circuits in holding that a treating physician is exempt from written report requirements under Fed. R. Civ. P. 26(a)(2)(B) "to the extent his opinions were formed during the course of treatment." *Goodman v. Staples The Office Superstore, LLC*, 644 F.3d 817, 826 (9th Cir. 2011). Thus, a treating physician may be allowed to opine even as to causation if the opinion was formed during the course of providing treatment, regardless of submission of an expert report. *Id*. at 825-26; *but see U.S. v. Urena*, 659 F.3d 903, 908 (9th Cir. 2011) (holding physician's opinion on issues of causation required expert testimony).

[6] Luttrell makes no argument as to the qualifications of the experts under the *Daubert* standard, except to refer to the Court to their attached CV's.

Luttrell has designated five of his treating physicians to testify as experts in this case, namely: Dr. Brady, Dr. Cleary, Dr. Oda, Dr. Tew, and Dr. Young. ECF No. 46, Att. #92 at 9-11. None of the five experts has been retained by Luttrell or provided an expert report under Fed. R. Civ. P. 26. Novartis moves to exclude the testimony of all five experts. The Court will address each doctor in turn.

1. Dr. Albert Brady

Dr. Brady is Luttrell's oncologist, and he prescribed Zometa® and Aredia® to Luttrell. ECF No. 46-92 at 9-10. Dr. Brady is expected to testify as to his care and treatment of Luttrell. *Id.* Plaintiff also designated him to testify that "consistent with his medical records, [] Mr. Luttrell likely had ONJ which was caused by his use of Zometa® and Aredia®" and "to rule out other possible causes as likely causes of Mr. Luttrell's BRONJ". ECF No. 46-92 at 10.

Novartis argues that Dr. Brady cannot offer opinions about what caused Luttrell's ONJ or rule out other causes because Dr. Brady "testified affirmatively" that he did not determine that Aredia® or Zometa® caused Luttrell's ONJ; and that, with the exception of myeloma, he did not rule out other causes of Luttrell's ONJ. ECF No. 44-1 at 9 (citing Brady dep. at 37-38, 55). Luttrell makes no cognizable argument as to why causation testimony by Dr. Brady is admissible; nor does he point to any evidence in the record that Dr. Brady has any opinion as to causation, aside from the bare assertion by Luttrell that Dr. Brady is designated

to testify that Luttrell's ONJ was "likely caused" by his use of Zometa® and Aredia®.

Luttrell fails to point to any opinion of Dr. Brady under oath and to a reasonable degree of medical certainty that Aredia® or Zometa® caused Luttrell's ONJ. Thus, the Court finds that Dr. Brady can offer no admissible testimony as to specific causation. Pursuant to Ninth Circuit precedent, Dr. Brady may offer testimony as to opinions formed during the course of treatment. *Goodman*, 644 F.3d at 825-26. Testimony by Dr. Brady within the confines of his professional knowledge in the course of treating Luttrell, including any diagnosis, is admissible. However, testimony as to the specific cause of Luttrell's injury is excluded.

2. Dr. Sean Cleary

Dr. Sean Cleary is a radiological oncologist who took scans of Luttrell's jaw. ECF No. 46-92 at 10. Dr. Cleary is designated by Plaintiff to testify that he "excluded multiple myeloma as a possible cause of Mr. Luttrell's jaw problems" and "as reflected in his records, he believed that Mr. Luttrell more likely than not was suffering from bisphosphonate induced osteonecrosis of the jaw." *Id.*

First, Novartis argues that Luttrell does not meet his burden to prove Dr. Cleary's is an expert in the causes and diagnosis of ONJ because Luttrell offers no evidence of Dr. Cleary's expertise. ECF No. 44-1 at 10. He was never deposed, no CV was provided, his online profiles do not mention expertise in either area,

and internet searches show no publications or lectures by Dr. Cleary on ONJ or bisphosphonates. *Id*. Second, Novartis contends that Luttrell has offered no testimony that Dr. Cleary has an opinion regarding causation of Mr. Luttrell's BRONJ that is held to a reasonable degree of medical certainty. *Id*. Luttrell responds that Dr. Cleary's medical report is a reliable basis for him to testify as to his one visit with Luttrell, since he ruled out multiple myeloma in Luttrell's jaw and was the first to diagnose Luttrell with BRONJ. ECF No. 46-92 at 9.

Aside from purely conclusory statements in his responsive briefing, Luttrell offers absolutely no evidence of Dr. Cleary's qualifications to provide expert testimony in this case.[7] Plaintiff claims Dr. Cleary will testify "as reflected in his records, he believed that Mr. Luttrell more likely than not was suffering from bisphosphonate induced osteonecrosis of the jaw." ECF No. 46-92 at 10. The problem is that is not what is reflected in Dr. Cleary's records. Luttrell himself indicates that Dr. Cleary's report only indicated a finding that Luttrell's jaw pain was "most consistent with osteonecrosis secondary to bisphosphonate therapy." ECF No. 46-91 at 7. Lacking from Dr. Cleary's record is any reasoning or

[7] It must be noted that the Court's job is made almost impossible by Luttrell's continual lack of argument or citation to the record to support his arguments.

methodology underlying this finding, much less any opinion on causation to a degree of medical certainty.

Due to the complete absence of any proffer as to Dr. Cleary's qualifications or opinions, the Court finds insufficient evidence to support Dr. Cleary's testimony on the element of causation. As discussed above, Dr. Clearly may offer testimony only as to opinions formed during the course of treatment. *Goodman*, 644 F.3d at 825-26.

3. Dr. Dolphine Oda

Dr. Dolphine Oda is an oral pathologist. ECF No. 46-92 at 11. She examined a bone specimen from Mr. Luttrell's jaw, and wrote a report stating that the bone was necrotic and that the sample was consistent with BRONJ. ECF No. 44-1 at 12. Dr. Oda is designated to testify that "consistent with her medical records, Mr. Luttrell likely had BRONJ." *Id*.

Novartis argues that any causation testimony by Dr. Oda is inadmissible, and points to testimony by Dr. Oda that she never formed an opinion "to a reasonable degree of certainty as to the cause of Mr. Luttrell's ONJ." ECF No. 44-1 at 11 (citing Oda dep. at 87-88). Moreover, Novartis argues that Dr. Oda herself testified that pathology alone, without additional clinical history, cannot distinguish between samples of ONJ from patients who have had bisphosphonate therapy and those who have not. *Id*. (citing Oda dep. at 73, 75, 80). Dr. Jackson,

Luttrell's retained expert on the issue of causation, also testified that Dr. Oda can only comment on histology, not the cause of Mr. Luttrell's condition. *Id*. (citing Jackson dep. I at 161-62).

Luttrell makes no discernible argument as to why Dr. Oda is qualified to offer testimony on causation. That said, the Court finds no evidence that Luttrell intends to offer Dr. Oda's testimony on the element of causation. Dr. Oda is designated to testify as to a diagnosis of BRONJ. ECF No. 46-92 at 11. Testimony by Dr. Oda as to her examination of the bone sample from Luttrell is clearly relevant and Novartis does not challenge her expertise or the scientific methodology underlying the examination. The Court finds that, consistent with *Goodman*, Dr. Oda may offer testimony as to opinions formed during the course of studying the histology of Luttrell's bone specimen, but not causation. *Goodman*, 644 F.3d at 825-26.

4. Dr. Darrell Tew

Dr. Darrell Tew was Luttrell's oral surgeon. ECF No. 49-92 at 11. "He is expected to testify, consistent with medical records and his communications with other treating physicians, that Mr. Luttrell likely has BRONJ caused by his use of bisphosphonates, Zometa® and Aredia®." *Id*.

First, Novartis argues that Luttrell does not meet its burden to prove Dr. Tew has the requisite experience to diagnose BRONJ or opine as the causes of Mr.

Luttrell's alleged BRONJ. ECF No. 44-1 at 12. Dr. Tew disclaims expertise in diagnosing BRONJ and testified that he is "not an expert in the AAOMS three-pronged approach." *Id*. (citing Tew dep. at 54-58). Dr. Tew also testified that he relied on Dr. Oda to help him determine if Luttrell had BRONJ. ECF No. 44-1 at 12-13 (citing Tew dep. at 43, 101-105). Second, Novartis argues that Dr. Tew did not form an admissible opinion as to causation, and that his testimony should be excluded. ECF No. 44-1 at 14. Novartis points to repeated testimony in Dr. Tew's deposition that he doesn't have an opinion on the cause Mr. Luttrell's alleged BRONJ, and the fact that he did not perform a differential diagnosis. ECF No. 44-1 at 13-14 (citing Tew dep. at 102, 105, 37-38, 85-89).

Luttrell fails to offer any argument as to why Dr. Tew is qualified to offer testimony on causation despite his explicit testimony that he formed no opinion regarding the cause of Luttrell's BRONJ. Thus, the Court finds that, consistent with *Goodman*, Dr. Tew may offer testimony only as to opinions he formed during the course of treatment, but that does not include testimony regarding causation. *See Goodman*, 644 F.3d at 825-26

5. Dr. Mark Young

Dr. Mark Young was Dr. Luttrell's dentist. ECF No. 46-92 at 10. Dr. Young is expected to testify as to his care and treatment of Luttrell. *Id.* Specifically, he is designated to testify about Luttrell's dental condition and

describe bone and tooth conditions, and "to rule out other probable causes of Mr. Luttrell's BRONJ." *Id*. Also, he is expected to testify that Dr. Tew "indicated that he believed that Mr. Luttrell has BRONJ caused by the use of bisphosphonates, Zometa® and Aredia®." ECF No. 46-92 at 10-11.

First, Novartis argues that Luttrell does not meet its burden to prove Dr. Young has the requisite experience to diagnose BRONJ or opine as the causes of Mr. Luttrell's alleged BRONJ. ECF No. 44-1 at 14. Dr. Young testified that he had never treated a patient with BRONJ besides Mr. Luttrell (allegedly), and he attended his first conference on bisphosphonates 4 years after he stopped treating Luttrell. *Id*. (citing Young dep. at 6, 34, 41-42). Second, even if he was qualified, Mr. Young testified in depositions that he had no opinion as to the cause of Luttrell's ONJ. *Id*. (citing Young dep. at 45-46, 50).

Once again, Luttrell makes no identifiable argument as to why Dr. Young is qualified to offer testimony on causation despite his testimony under oath that he had no opinion as to what caused Luttrell's ONJ. Thus, the Court finds, consistent with *Goodman*, that Dr. Young may offer testimony only as to his opinions on Luttrell's bones and tooth conditions formed while treating Luttrell as his dentist. *See Goodman*, 644 F.3d at 825-26. These opinions cannot include causation opinions and cannot incorporate any purported opinion of Dr. Tew as to causation, especially in light of the fact that, as described above, Dr. Tew himself renounced

any opinion he had as to causation.

B. Causation Testimony by Dr. Jackson

As outlined in detail above, the testimony of an expert is only admissible (1) if the expert has sufficient expertise under Rule 702(a), (2) the testimony is relevant, and (3) the testimony is reliable. *See Daubert*, 509 U.S. at 589. Novartis challenges the testimony of Luttrell's retained expert Dr. Richard Jackson ("Dr. Jackson") on all three grounds. ECF No. 44-1 at 15-25. Luttrell responds generally that all of these criticisms go to the weight of the testimony instead of the admissibility. ECF No. 46-92 at 9.

1. Expertise in ONJ Causation

According to Rule 702(a), a witness may be qualified as an expert by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702(a). Novartis argues that Dr. Jackson does not have the necessary knowledge or experience to testify as to whether Aredia® and Zometa® caused Luttrell's ONJ, or as to how Luttrell's "other risk factors" did not cause ONJ. ECF No. 44-1 at 15. Novartis points to a litany of facts to support its claim, including: 1) Dr. Jackson never published an article or gave a lecture on bisphosphonates or ONJ (Jackson dep. at 47-48, 59-61); 2) Dr. Jackson "appears to have no particular expertise" on several areas "concerning bisphosphonates and ONJ" including how many doses of pamidronate or Zometa® are sufficient to create a risk of ONJ; 3) Dr. Jackson has

no opinion about the mechanism of action by which bisphosphonates may cause ONJ; 4) Dr. Jackson did not consider himself an expert until after he was retained as an expert (i.e. he testified he was not an expert at the time of Mr. Luttrell's injury) and only started relying on literature concerning ONJ and bisphosphonates after he was retained as an expert; 5) Dr. Jackson treated a maximum of 15 people with ONJ subsequent to bisphosphonate therapy; 6) Dr. Jackson does not have the requisite expertise to eliminate causes of ONJ other than bisphosphonates because he has never "seen a case of ONJ that he has attributed to chemotherapy, corticosteroids, periodontal disease, bone metastases, or osteomyelitis if it has lasted over 8 weeks." ECF No. 44-1 at 15-17.

Luttrell responds with a list of qualifications from Dr. Jackson's curriculum vitae including his education and practice in the field of oral and maxillofacial surgery. *See* ECF No. 46-92 at 7-8. Dr. Jackson graduated from the University of San Francisco Dental School. *Id*. He practiced dentistry in the U.S. Air Force from 1975-1978, and then practiced oral surgery in a hospital-based practice until 1988. *Id*. He has been a practicing oral and maxillofacial surgeon since 1988 and is a member of both the American College of Oral and Maxillofacial Surgeons and the American Board of Oral and Maxillofacial Surgeons. *Id*. Dr. Jackson was also hired by UC Davis Medical Center to conduct a pre-study screening of patients prior to their inclusion in a BRONJ study. *Id*. Additionally, seemingly in response

to Novartis' contention that Dr. Jackson had "no opinion" on dosage requirements to cause ONJ, Luttrell points to testimony by Dr. Jackson that BRONJ is "dose and time dependent – one cannot separate doses and indicate that this dose caused BRONJ and that dose did not." *Id*. (citing Jackson dep. at 179).

The Court finds that Dr. Jackson is sufficiently qualified to render a causation opinion. Rule 702 does not require an expert to publish articles or give lectures in order to qualify to give expert testimony, nor does it require a medical expert to review a certain amount of medical literature. In addition, Dr. Jackson's lack of opinion on several areas concerning bisphosphonates does not automatically disqualify him from testifying as a medical expert as to causation, nor does the fact that he has not previously diagnosed ONJ as attributable to risk factors other than bisphosphonate. Finally, while treating 15 patients with a BRONJ diagnosis may appear to be a small number, this does not discount the experience and knowledge amassed by Dr. Jackson in treating many more patients as an oral and maxillofacial surgeon.[8] Thus, the Court finds the combination of

[8] Novartis also contends that Dr. Jackson's claim as the "primary referral source" for treatment of BRONJ is related to his acceptance of medical insurance and referrals, and is not related to his expertise. ECF No. 44-1 at 17. The Court rejects

Dr. Jackson's education and his experience treating patients as an oral and maxillofacial surgeon, including patients with ONJ, adequately qualifies him to give expert testimony under the dictates of Rule 702.

2. Relevance or "fit" of Dr. Jackson's Causation Opinion

Under Federal Rule of Evidence 702 an expert may testify if his or her knowledge "will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. Thus, in order to be admissible under the guidelines of *Daubert*, an expert's testimony must "fit." *See Daubert*, 509 U.S. 579, 591. In other words, it must be relevant, and "logically advanc[e] a material aspect of the proposing party's case." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995)("*Daubert II*").

Novartis argues that the issue in this case is whether Zometa® and Aredia® caused Luttrell's ONJ, and therefore, Dr. Jackson's testimony does not "fit" this case because he only opines about whether Luttrell had BRONJ instead of whether Luttrell's ONJ was caused by bisphosphonate therapy with Aredia® or Zometa®. ECF No. 44-1 at 18-19 (emphasis added). Specifically, Novartis relies on

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this attack. What is important is that Dr. Jackson has experience with patients, not the reason he has patients.

testimony by Dr. Jackson differentiating a diagnosis of BRONJ under the AAOMS definition as ONJ "related" to bisphosphonates instead of "caused" as follows:

> Q. And in that scenario then, it would be the pamidronate that you would be saying caused the jaw necrosis, correct?
> A. Not cause.
> Q. Well, you would still call it bisphosphonate-related ONJ, correct?
> A. Well, they've specifically used the term "related." They didn't use the word "cause," it's related …. That's very critical to their definition.

ECF No. 44-1 at 18 (citing Jackson dep. I at 174-176). Novartis asks the Court to exclude Dr. Jackson's expert testimony on causation because his report and his testimony only address a diagnosis of BRONJ, as opposed to the specific cause of Luttrell's ONJ, and are therefore not helpful to the jury.

Luttrell responds only that Dr. Jackson "clearly opines that Mr. Luttrell had BRONJ." ECF No. 46-92 at 8. However, Luttrell's argument is completely misplaced because Novartis is arguing that Dr. Jackson's opinion on causation should be excluded, not his opinion as to diagnosis. ECF No. 44-1 at 17-19. In his expert report, Dr. Jackson does state that bisphosphonates have "shown a propensity to cause jaw necrosis in patients" both now and in the past. ECF No. 47-22 at 2. However, this statement goes only to general causation, instead of the specific causation element necessary to prove a products liability claim, namely, that Aredia® or Zometa® were a proximate cause of Luttrell's ONJ.

Despite being a retained expert by Luttrell, Dr. Jackson never definitely opines on the record that Luttrell's ONJ was caused by Aredia® or Zometa®.

Thus, the question the Court must answer is whether the lack of an affirmative statement as to causation is fatal to the admissibility of his testimony. On the one hand, the deposition testimony cited by Novartis must be viewed in the correct context. Dr. Jackson does not declare that bisphosphonates do not cause ONJ, he simply clarifies the exact medical definition of BRONJ according to the AAOMS definition. In addition, in the deposition testimony provided to the Court, Dr. Jackson is never directly asked whether he believes that Aredia® or Zometa® caused Luttrell's ONJ, nor does he expressly disclaim any opinion on the causation issue. On the other hand, Luttrell does not point out, nor can the Court find, any affirmative statement by the appropriate standard of medical certainty that Luttrell's ONJ was caused by Zometa® or Aredia®.

In making its decision, the Court relies on the exact dictates of Rule 702 and the *Daubert* requirements. Based on the record before the Court, there is simply not enough evidence one way or the other to determine whether Dr. Jackson's testimony will be helpful to the jury on the issue of causation. However, the blurred lines between causation and diagnosis in this case, which Dr. Jackson himself pointed out, is in and of itself a reason to have an expert who can logically advance this material element of the case. By the slightest of margins, the Court finds that Novartis' argument as to the relevance of Dr. Jackson's testimony goes only to its weight and not its admissibility.

3. Reliability of Dr. Jackson's Causation Opinion

In order to determine the reliability of expert testimony, the court must analyze "whether the reasoning or methodology underlying the testimony is scientifically valid." *Daubert*, 509 U.S. at 592. The Court in *Daubert* suggested a non-exclusive list of factors a court could consider in determining the reliability of expert testimony, including (1) whether a theory or technique can be tested, (2) whether it has been subjected to peer review and publication, (3) whether there is a known or potential rate of error, and (4) whether the theory or technique is "generally accepted" in the scientific community." *Daubert*, 509 U.S. at 593-594. On remand from the Supreme Court, the Ninth Circuit further explained that if the testimony was not based on independent research, "the party proffering it must come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.'" *Daubert II*, 43 F.3d at 1317-1318. In addition, "a very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of litigation, or whether they have developed their opinions expressly for the purpose of testifying." *Id.* at 1317.

A medical opinion on causation that is based on a reliable differential diagnosis is admissible under *Daubert*. *See Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1057 (9th Cir. 2003) ("expert testimony that neglects to consider a

hypothesis that might explain the clinical findings under consideration may also be unreliable."). Moreover, the expert must explain why alternative hypotheses as to causation are ruled out using scientific methods and procedures. *Id*. (this elimination must not be founded on "subjective beliefs or unsupported speculation").

Novartis presents a host of arguments as to why Dr. Jackson's testimony on causation is unreliable due to "methodological inconsistencies." ECF No. 44-1 at 20-25. First, Novartis argues that Dr. Jackson's testimony is unreliable because he did not follow his own methodology for establishing causation. ECF No. 44-1 at 20-21. Namely, he did not perform a clinical evaluation of Luttrell and he did not review radiologic imaging or send a bone specimen for histological evaluation. *Id*. Second, Novartis contends that Dr. Jackson did not perform a sufficient differential diagnosis when analyzing the cause of Mr. Luttrell's ONJ because he provided no reliable basis for ruling out a multitude of other risk factors.[9] ECF No. 44-1 at 21. Third, Novartis argues that Dr. Jackson's causation testimony is inadmissible

[9] This list of risk factors includes: dental infection, multiple myeloma, chemotherapy, corticosteroid therapy, mandibular tori, poor dental hygiene, periodontal disease, xerostomia, dental trauma, history of heavy smoking, failing of root canal, advanced age, and other unknown causes. ECF No. 44-1 at 21.

because he could not rule out exactly what contribution those same risk factors had in causing Luttrell's ONJ. ECF No. 44-1 at 24 (citing Jackson dep. at 190-93).

Luttrell responds that Dr. Jackson did reliably rule out other risk factors including osteomyelitis, corticosteroid use, osteoradionecrosis, and "other afflictions." ECF No. 46-92 at 8 (citing Jackson dep. at 190, 193). Dr. Jackson testified that "BRONJ is a unique signature injury that behaves differently and lasts longer than other possible causes such as osteoradionecrosis or osteomyelitis." *Id*. (citing Jackson dep. at 183, 184, 187). He also testified that

> the initial lesion discovered by Cleary was three by three millimeters, and it got worse not better over a long period of time until it finally fell off. That's his whole mandibular tori. Now, is this the sort of thing that you would see in a nonbisphosphonate patient, the answer is no. You don't see this sort of thing.

Id. (citing Jackson dep. at 187). After an exhaustive review of Dr. Jackson's deposition, the Court also found testimony that differentiates between the list of potential other causes, or contributing factors, of ONJ because "they affect the host, but they don't affect the bone. The only thing that affects the bone is the bisphosphonate drug. And that's what causes the behavior that's unique to bisphosphonate osteonecrosis." Jackson dep., ECF No. 47- 23 at 192-193.

However, Luttrell does not cite to any portion of Dr. Jackson's testimony or Dr. Jackson's three page expert report that indicates "objective, verifiable evidence that [his] testimony is based on 'scientifically valid principles.'" *Daubert II*, 43

F.3d at 1317-1318. Luttrell has not come forward with any evidence that Dr. Jackson performed a valid differential diagnosis, using scientific methods and procedures, to explain why alternative hypotheses as to causation were ruled out in Luttrell's case. Dr. Jackson's report indicates that he reviewed Luttrell's medical records and diagnosed him with BRONJ based on the AAOMS definition, but it provides no further assessment of any other risk factors and why they should be ruled out as causes or contributing factors, nor does it affirmatively state that Luttrell's ONJ was caused by Zometa® or Aredia®. ECF No. 47-22. Several bald assertions buried in the transcript of a deposition as to the "unique" behavior of BRONJ as compared to other causes of ONJ or other contributing factors does not qualify Dr. Jackson's testimony as sufficiently reliable under *Daubert*. Thus, the Court finds that Dr. Jackson's opinions as to causation are unsupported by a reliable scientific methodology, and grants Novartis' motion to exclude his causation testimony.

II. Summary Judgment

The court may grant summary judgment in favor of a moving party who demonstrates "that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In ruling on a motion for summary judgment, the court must only consider admissible evidence. *Orr v. Bank of America, NT & SA*, 285 F.3d 764 (9th Cir. 2002). The

party moving for summary judgment bears the initial burden of showing the absence of any genuine issues of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Thus, the defendant moving for summary judgment must show "(1) that there is no genuine issue of material fact, or alternately, (2) that the plaintiff lacks competent evidence to support an essential element of his or her claim." *Fabrique v. Choice Hotels Intern., Inc.*, 144 Wash. App. 675, 685 (Ct. App. 2008).

The burden then shifts to the non-moving party to identify specific facts showing there is a genuine issue of material fact. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Id*. at 252.

For purposes of summary judgment, a fact is "material" if it might affect the outcome of the suit under the governing law. *Id.* at 248. Further, a material fact is "genuine" only where the evidence is such that a reasonable jury could find in favor of the non-moving party. *Id.* The court views the facts, and all rational inferences therefrom, in the light most favorable to the non-moving party. *Scott v. Harris*, 550 U.S. 327, 378 (2007).

A. Causation

The Washington Products Liability Act governs the issues presented in this

motion. *See* Wash. Rev. Code 7.72 *et seq*. Under Washington law, proximate cause in a products liability action is composed of two elements: (1) cause in fact and (2) legal causation. *Hartley v. State*, 103 Wash.2d 768, 777 (1985). A cause in fact is a cause but for which the plaintiff's injury would not have happened. *Gall v. McDonald Industries*, 84 Wash. App. 194, 207 (Wash. Ct. App. 1996); *see also McCoy v. American Suzuki Motor Corp.*, 136 Wash.2d 350, 357 (1998) ("[c]ause in fact asks whether 'there was sufficiently close, actual, causal connection between defendant's conduct and the actual damage suffered by plaintiff'"). In other words, if the event would have occurred regardless of the defendant's actions, that action is not the proximate cause of the injury. *Davis v. Globe Mach. Mfg. Co., Inc.*, 102 Wash.2d 68, 74 (1984). The issue of causation is "generally not susceptible to summary judgment. However, 'when reasonable minds could reach but one conclusion, questions of fact may be determined as a matter of law.'" *Ruff v. County of King*, 125 Wash. 2d 697, 703-704 (1995) (internal citations omitted).

1. Expert Testimony Establishing Causation

Expert medical testimony is often "necessary to establish causation where the nature of the injury involves 'obscure medical factors which are beyond an ordinary lay person's knowledge, necessitating speculation in making a finding.'" *Fabrique*, 144 Wash. App. at 685. Specifically, expert testimony must

demonstrate that the defendant's product "probably" or "more likely than not" caused the injury, rather than "might have", "could have", or "possibly did." *Id.* at 688. The medical testimony must be based on a reasonable degree of medical certainty according to the facts of the case, as opposed to unsupported speculation. *McLaughlin v. Cooke*, 112 Wash.2d 829, 836 (1989). The defendant has the initial burden to show that plaintiff lacks admissible expert evidence, at which point the burden shifts to the plaintiffs to present admissible expert testimony to establish proximate cause. *See Fabrique*, 144 Wash. App. at 685.

Novartis argues that if the Court grants its *Daubert* motion to exclude causation testimony by Luttrell's experts, then Luttrell will have no admissible evidence to prove medical causation, and therefore Novartis would be entitled to judgment as a matter of law on all Luttrell's claims. ECF No. 44-56 at 10. Additionally, Novartis argues that even if Luttrell's expert Dr. Jackson is allowed to testify, Luttrell still lacks sufficient evidence to overcome summary judgment because the expert report only discloses a diagnosis of bisphosphonate-related osteonecrosis of the jaw ("BRONJ") instead of an opinion about whether the bisphosphonates caused the ONJ, and Dr. Jackson admits he cannot rule out other factors that contributed to Luttrell's ONJ. ECF No. 44-56 at 11. Luttrell responds that he has produced sufficient evidence of causation to carry his burden. ECF No. 46-91 at 11.

Luttrell maintains that Dr. Jackson did testify that use of Aredia® and Zometa® were the likely cause of Luttrell's injury.[10] ECF No. 46-91 at 13. Luttrell also refers to testimony from Dr. Jackson in his deposition explaining why comorbidities such as osteomyelitis or periodontal disease did not cause Mr. Luttrell's necrotic bone, and notes that his testimony was based on his experience and a "differential diagnosis method." ECF No. 46-91 at 13.

The Court acknowledges that there can be more than one proximate cause of an injury and it is not necessary to rule out all other possible causes of Mr. Luttrell's injury in order to survive summary judgment. However, there is a complete absence of affirmative evidence in the record that Aredia® and Zometa® more likely than not caused Luttrell's ONJ. In addition, as indicated in section I supra, the Court has excluded causation testimony by all of Luttrell's treating physicians, as well as his retained expert on causation Dr. Jackson due to a lack of evidence offered by Luttrell to support the reliability of his testimony. Without

[10] This general statement by Luttrell referring to the deposition of Dr. Jackson does not cite to "particular parts of materials in the record" as required under Fed. R. Civ. P. 56(c). The Court was unable to find a definitive statement by Dr. Jackson in his testimony that Aredia® or Zometa® was the "likely cause" of Luttrell's injury.

any admissible testimony as to legal causation, as opposed to diagnosis, there can be no genuine issue of material fact on the causation issue.

2. Product Identification (Aredia® v. Generic Pamidronate)

"Under traditional product liability theory, the plaintiff must establish a reasonable connection between the injury, the product causing the injury, and the manufacturer of that product. In order to have a cause of action, the plaintiff must identify the particular manufacturer of the product that caused the injury." *Braaten v. Saberhagen Holdings*, 165 Wash.2d 373, 396 (2008) (*citing Lockwood v. AC & S, Inc.*, 109 Wash.2d 235, 245 (1987)).

No one disputes that Luttrell received a single dose of Zometa®. Novartis contends that Luttrell cannot prove that he actually received Aredia® instead of generic pamidronate, and therefore he cannot prove that Aredia® caused his injury.[11] ECF No. 44-56 at 12. In support of this argument, Novartis offers three facts: (1) during the time period that Luttrell received the drug, Aredia® constituted one percent of the pamidronate market; (2) Dr. Brady, the prescribing oncologist at the center where Luttrell received the drug stated that "the odds are

[11] Novartis also argues against a hypothetical argument by Luttrell that his injury was caused by the single dose of Zometa®. ECF No. 44-56 at 12. Luttrell does not, in fact, offer this argument. Therefore, the Court declines to consider it.

overwhelming that we would use, once it is off patent, is generic,"[12] ECF No. 44-56 at 12 (citing SUF ¶ 15, 16, 50); and (3) plaintiff's oncologist's purchasing records that show only generic pamidronate was purchased from December 8, 2005 through November 17, 2009, accounting for the last five of the eleven doses Luttrell received before he stopped taking the drug.

Luttrell responds that these arguments are "highly speculative" and refers to testimony, and accompanying medical records, by Dr. Brady that he gave Luttrell "Zometa®" and then "Aredia®" from mid-2005 to mid-2006. ECF No. 46-91 at 12 (citing Brady dep. at 70, 71). Luttrell has not challenged his oncologist's purchasing records showing that his last five doses must have been generic pamidronate.

Regardless of the market share of Aredia® at the time that Luttrell received his treatments, this statistic is simply not enough for the Court to find that Novartis is entitled to summary judgment. "Overwhelming odds" are not adequate to establish that there is absolutely no genuine issue of material fact as to whether Luttrell was given six initial doses of Aredia® or generic pamidronate. While the

[12] Aredia® went off patent in 2001. ECF No. 44-56 at 12. This fact is undisputed by Luttrell.

Court is highly skeptical that Luttrell received any Aredia®,[13] the Court finds a genuine issue of material fact exists as to whether or not Luttrell was given six initial doses of Aredia® as opposed to generic pamidronate.

B. Strict Liability under the WPLA

The WPLA preempted common law theories of negligence in product liability claims, and created a single cause of action for product-related harms. *See Wash. State Phys. Ins. Ex. v. Fisons Corp.*, 122 Wash.2d 299, 322-323 (1993); *see also Garza v. McCain Foods, Inc.*, 124 Wash. App. 908, 916 (Ct. App. 2004) ("[t]he act imposes strict liability on the manufacturer of a defective product for resulting injuries"). Thus, in order to recover on a products liability claim against a manufacturer under Washington law, the Plaintiff must prove that "the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided." Wash. Rev. Code § 7.72.030(1).

[13] The Court is equally skeptical that the initial six doses could be the proximate cause of Luttrell's injury, as opposed to the last five doses of generic pamidronate administered immediately preceding his injury. Of course, no expert speaks to this quandary.

1. Adequacy of Warning

Washington has expressly adopted Restatement (Second) of Torts § 402A comment k, which limits strict liability of manufacturers of prescription drugs in situations where the product is properly prepared and accompanied by adequate warnings. *See Terhune v. A.H. Robins Co.*, 90 Wash.2d 9, 12-14 (1978). Thus, in order to recover on a strict liability claim against a drug manufacturer, a plaintiff must prove that the manufacturer did not satisfy its duty to warn. *See Young v. Key Pharmaceuticals, Inc.*, 130 Wash.2d 160, 169 (1996) (plurality opinion) (finding that whether defendant satisfied duty to warn is governed by negligence standard). Washington follows the learned intermediary doctrine, so the manufacturer's duty is satisfied if the product is properly labeled and the prescribing physician has adequate warning as to any possible dangers. *See Terhune*, 90 Wash.2d at 14 ("the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.").

A warning may be adequate if it provides specific and detailed information about the risks of using the drug. *Estate of LaMontagne v. Bristol-Myers Squibb*, 127 Wash. App. 335, 344 (Ct. App. 2005).

> To determine whether a warning is adequate requires an analysis of the warnings as a whole and the language used in the package insert. The court must examine the meaning and context of the language and the manner of expression to determine if the warning is accurate, clear and consistent and

> whether the warning portrays the risks involved in taking the prescription drug.

Id. at 345.

The label for Zometa® and Aredia®, which was effective in February 2004 for Zometa® and March 2004 for Aredia®, read:

> ONJ has been reported in patients with cancer receiving treatment regimens including bisphosphonates…A dental examination with appropriate preventative dentistry should be considered prior to treatment with bisphosphonates for patients with concomitant risk factors (e.g. cancer, chemotherapy, corticosteroids, poor oral hygiene). While on treatment, those patients should avoid invasive dental procedures if possible.

ECF No. 44-56 at 15.

Novartis contends that Luttrell's situation "paralleled" the label because Dr. Brady diagnosed him with myeloma in 2005 and was aware that the course of treatment "would require Mr. Luttrell to receive chemotherapy and corticosteroids, and Mr. Luttrell had a history of diagnosed, but largely untreated, periodontal disease." *Id*. Thus, Novartis argues that Dr. Brady's "admitted awareness" of the alleged side effects of a prescribed pharmaceutical is sufficient to prove adequate warning under the requirements of comment k. *See Terhune*, 90 Wash.2d at 17 (holding the duty to warn was satisfied under comment k because the physician was "admittedly aware" of possible dangers but decided to prescribe the product because the risk was not significant). In support of this argument, Novartis cites to testimony by Dr. Brady that he "suspected by then he knew" (referring to when he

prescribed the drugs to Luttrell) of a possible connection between bisphosphonates and ONJ before he prescribed Zometa® and Aredia® to Luttrell.[14] ECF No. 44-56 at 15-16 (citing SUF ¶ 77, Brady dep. 14, 74). Also Novartis contends that Dr. Brady must have been aware of the possible danger because he called Dr. Young, Luttrell's dentist, to request that he x-ray Luttrell's jaw "to inform him of the association between bisphosphonates and ONJ and the importance of monitoring [Luttrell's] jaw bone." *Id*. (citing Young dep. at 39).

Luttrell cites no Washington law in his response; instead he relies on a previous holding by "this Court" that found plaintiff had enough evidence to rebut a statutory presumption in Florida law that its drugs were not unreasonably dangerous.[15] Luttrell argues that "what is good enough to defeat the statutory presumption in Florida is good enough to defeat summary judgment brought under

[14] Novartis relies on the fact that it sent letters to hematologists, urologists, oral surgeons and oncologists pointing out an association between bisphosphonates and ONJ in 2004, and a similar letter to oral surgeons in 2005, to prove that Dr. Brady was aware of the connection between bisphosphonates and ONJ. ECF No. 44-56 at 15.

[15] The Court presumes Luttrell's reference to "this Court" is referencing previous holdings by the MDL Court.

the Washington law." And further instructs this Court to "follow its own precedent and deny summary judgment here on the adequacy of warning." ECF No. 46, Att. #91 at 11. However, the Florida statute referred to by Luttrell involves a rebuttable presumption that a product is not defective or unreasonably dangerous if manufacturer complied with federal codes, statutes, rules and regulations. *See In re Aredia® and Zometa® Products Liability Litigation*, 2010 WL 813459, *1 (2010). This statute makes no reference to adequate warnings and is therefore distinguishable from Washington law.

The Court finds the arguments from both parties to be inadequate. Luttrell has made absolutely no argument as to why, under Washington law, the warnings were not adequate. As to Novartis' argument, there is insufficient evidence in the record to support its contention that Dr. Brady was "admittedly aware" of the connection between bisphosphonates and ONJ, thereby satisfying the adequacy of warning requirement for the purposes of comment k. Dr. Brady's testimony that he "suspected he knew" about a connection between bisphosphonates and ONJ is simply not definite enough to find that no genuine issue of material fact exists when viewed in the light most favorable to the non-moving party. The Court emphasizes its dissatisfaction with Luttrell's failure to cite any applicable Washington law on this issue.

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2. Proximate Cause

As noted above, cause-in-fact is generally a question for the jury, however, "when the facts are undisputed and the inferences therefrom are plain and incapable of reasonable doubt or difference of opinion, factual causation may become a question of law for the court." *Baughn v. Honda Motor Co., Ltd.*, 107 Wash.2d 127, 142 (1986). Under Washington law, the plaintiff must prove that if adequately warned of the risk, "they would have treated the product differently and avoided the harm." *Ayers By and Through Smith v. Johnson & Johnson Baby Products Co.*, 59 Wash. App. 287, 291 (Ct. App. 1990). In other words, the Court must consider whether a "different, increased warning" would have persuaded the plaintiff, or under the learned intermediary doctrine, his physician, "to take a different course of action." *See Laisure-Radke v. Par Pharmaceutical, Inc.*, 426 F.Supp.2d 1163, 1173 (W.D. Wash. 2006).

Novartis argues that Luttrell cannot sustain his burden to prove proximate cause because he cannot prove that stronger warnings would have affected Dr. Brady's decision to prescribe Aredia® and Zometa®. ECF No. 44-56 at 16-17. In support, Novartis points out that Dr. Brady continued prescribing Aredia® after Luttrell was diagnosed with ONJ because he believed the benefits outweighed the risks, and he continues to prescribe Zometa® and Aredia® to other patients as they remain standard of care drugs. ECF No. 44-56 at 17 (citing SUF ¶ 61, 62). Most

significantly, Dr. Brady and Luttrell agreed to restart the Aredia® protocol on May 2, 2007, two months after Luttrell filed this lawsuit, so both Dr. Brady and Luttrell were aware of the possible dangers of bisphosphonates, but still decided to use the drug. *Id*.

Luttrell responds that there is a genuine issue of material fact as to proximate cause, and "[i]f [Novartis] had adequately warned Mr. Luttrell of the risk, he simply would not have taken the drug as he testified."[16] ECF No. 46-91 at 14. He argues there is "at least circumstantial evidence" that Dr. Brady noted flu like symptoms Mr. Luttrell experienced after his first dose of Zometa®, and wrote in his medical records "[i]f he has the same problems [fatigue, fevers, chills, and anthralgias] he is going to have to do without prophylaxis for his bones" and "we can just can this whole bisphosphonate thing" if those symptoms continued. *Id*. (citing Brady dep. at 21, 24, 25).

[16] Luttrell also encourages the Court to adopt the "read and heed" presumption accepted by "other brethren states". ECF No. 46, Att. #91 at 15. Under this doctrine, a court will presume that had adequate warning been given it would have been heeded. *Id*. This presumption is not currently recognized in Washington law, which law the Court must apply in this case.

The legal standard for the Court to remove the issue of causation from the jury is extremely high. There is compelling evidence that Dr. Brady and Luttrell would have taken the same course of action even if the warnings about BRONJ were increased or different. The Court finds that the facts presented and inferences therefrom are absolutely "incapable of reasonable doubt or difference of opinion." *Baughn*, 107 Wash.2d at 142 (emphasis added). The Court performed a comprehensive review of Dr. Brady's testimony because under the learned intermediary doctrine, recognized in Washington, the pertinent question the Court must answer is whether Dr. Brady as the prescribing physician would have taken a different course of action if the warning was different.[17]

At no time in his deposition testimony does Dr. Brady unequivocally state that he would have taken a different course of action if provided with increased warnings. There are several portions of Dr. Brady's testimony where he expresses

[17] Novartis focuses on whether Dr. Brady would have "prescribed" Aredia® (or pamidronate) if the warnings were stronger. However, the Court recognizes that under Washington law, the appropriate standard is broader and includes whether the prescribing physician would have "taken a different course of action" or "treated the drug differently." *See Laisure-Radke*, 426 F.Supp.2d at 1173; *Ayers*, 59 Wash. App. at 291.

reservations about using bisphosphonates to treat Luttrell. First, a note in the medical record from Luttrell's doctor visit on July 17, 2006 identifies that Dr. Brady discontinued the Aredia® treatment as follows:

> Q. And it says "His last Aredia® was two months ago, after which time he and I agreed it should be discontinued."
> A. Yes.
> Q. Why did you discontinue Aredia®?
> A. I believe it was because of the jaw difficulty he was having

Brady dep., ECF No. 47-18 at 26. According to Dr. Brady's deposition testimony he recorded further "misgivings" at Luttrell's doctor visit one week later as follows: "I have misgivings about the current recommendation that is to continue bisphosphonates no matter what. I am not sure what the needs in [Luttrell's] case are worth whatever risk may be incumbent on continuing the bisphosphonates." Brady dep., ECF No. 47-18 at 34.

However, almost 2 years later, in March of 2008, Dr. Brady noted in his records that "[w]e are continuing the Aredia® intermittently, since I do not think it can make his jaw worse." Brady dep., ECF No. 47-18 at 56. Dr. Brady also testified that at this time "one had to weigh the benefits against the risks and make a decision about what the best thing to do was at the time…. with [Luttrell] I became concerned and remained concerned that he's achieved substantial gain in terms of the quality and durability of his remission from bisphosphonates." Brady dep., ECF No. 47-18 at 57. And finally, Dr. Brady testified that he and Luttrell

had "lengthy discussions about the pro and cons" of re-starting the Aredia® treatments and "who better than [Luttrell] to know what the risks were and whether he was willing to take those risks or not." Brady dep., ECF No. 47-18 at 75.

Dr. Brady and Luttrell agreed to restart the Aredia® protocol on May 2, 2007, two months after Luttrell filed this lawsuit, so both Dr. Brady and Luttrell were aware of the possible dangers of bisphosphonates, but still decided to use the drug. While one could argue that the dosage and frequency were altered, the fact is not a single expert, including Luttrell's, has an opinion on what quantity would be safe and what quantity would produce adverse effects. Restarting the drug after filing the lawsuit is powerful and conclusive evidence that is incapable of a difference of opinion by any reasonable trier of fact. The Court is thoroughly convinced that there is no genuine issue of material fact as to whether Dr. Brady and Luttrell would have taken "the same course of action" if the warnings about BRONJ were different. Accordingly, Luttrell cannot prove proximate causation.

C. Implied Warranty

Novartis contends that Luttrell presents no evidence that either Zometa® or pamidronate/Aredia® were not merchantable or unfit for their ordinary purpose. *See* Wash. Rev. Code 62A.2-314. Instead, both Dr. Brady and Luttrell's own experts acknowledge the benefits of Aredia® and Zometa®. ECF No. 44-56 at 23. This is further evidenced by the fact that Dr. Brady resumed prescribing Aredia®

to Luttrell even after he developed ONJ and after he filed this lawsuit. *Id*. Luttrell does not respond to this argument in his responsive briefing. Based on the argument by Novartis and the record before the Court, it finds no genuine issue of material fact exists as to Luttrell's implied warranty claim and grants summary judgment

As a final matter, Luttrell expressly conceded that his claims of express warranty, manufacturing defect, and negligent design claims should be dismissed.

ACCORDINGLY, IT IS HEREBY ORDERED:

1. Defendant's Motion to Exclude Causation Testimony by Plaintiff's Experts (ECF No. 43-53) is **GRANTED**.
2. Defendant's Motion for Summary Judgment (ECF No. 44-55) is **GRANTED**.

The District Court Executive is hereby directed to enter this Order and provide copies to counsel, enter judgment for the Defendant dismissing this action and **CLOSE** the file.

DATED this 1st day of October, 2012.

s/ Thomas O. Rice

THOMAS O. RICE
United States District Judge