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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

John D'Agnese and Barbara D'Agnese,

Plaintiffs,

v.

Novartis Pharmaceuticals Corporation,

Defendant.

No. CV-12-00749-PHX-JAT

ORDER

Pending before the Court are: (1) Defendant's Motion for Summary Judgment on Specific Medical Causation (Doc. 110); (2) Defendant's Motion for Summary Judgment on Inadequate Warnings and Remaining Claims (Doc. 112); and (3) Defendant's Motion for Summary Judgment on Plaintiffs' Punitive Damages Claim (Doc. 114). The Court now rules on the Motions.

I. BACKGROUND[1]

The Court previously set forth the Background of this case as follows:

> This case is part of "Wave III" of a multidistrict litigation in the United States District Court for the Middle District of Tennessee (the "MDL Court"). In their Second Amended Complaint (Doc. 1), Plaintiffs allege that Defendant Novartis Pharmaceuticals Corporation ("Defendant" or

[1] The Parties use the acronyms "BONJ," "BRONJ," and "BIONJ" to refer to bisphosphonate-related osteonecrosis of the jaw. Accordingly, the Court has also used the terms interchangeably throughout this Order.

> "NPC") produces and markets the drugs Aredia® and Zometa®.
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> Plaintiffs allege that Aredia® and Zometa® are classified as bisphosphonates and are prescribed for the management of metastatic disease to the bone and other bone diseases and conditions. Plaintiffs allege that Aredia® was the first generation version of Zometa®. Plaintiffs further allege that these drugs cause and precipitate osteonecrosis of the jaw or maxilla bone. Plaintiffs allege that osteonecrosis is bone death of an area of the bone, which is a permanently disfiguring and painful condition, which can result in the complete loss of the patient's jaw bone.
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> Plaintiff John D'Agnese ("Mr. D'Agnese") used Aredia® and Zometa® to treat multiple myeloma bone disease, a disease that Mr. D'Agnese was diagnosed with in 1995. Mr. D'Agnese was also prescribed chemotherapy with corticosteroids, radiation treatments, and two stem cell implants to treat the multiple myeloma. Plaintiffs allege that Mr. D'Agnese suffered osteonecrosis of the jaw ("ONJ") [] as a result of taking Aredia® and Zometa®. Plaintiffs assert that Mr. D'Agnese was given forty-seven doses of Aredia® from December 3, 1998 to May 28, 2002 and forty-two doses of Zometa® from June 28, 2002 to October 11, 2005.
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> After completion of pretrial proceedings, this case was transferred from the MDL Court to this Court.

(Doc. 139); *D'Agnese v. Novartis Pharmaceuticals Corp.*, 2013 WL 321773, at *1 (D. Ariz. Jan. 28, 2013).

In their Second Amended Complaint, Plaintiffs assert the following claims against Defendant: (1) Strict Liability (Count I); (2) Negligence—Negligent Manufacture (Count II); (3) Negligence—Failure to Warn (Count III); (4) Breach of Express Warranty (Count IV); (5) Breach of Implied Warranty (Count V); and (6) Loss of Consortium (Count VI).

Defendant now moves for summary judgment: (1) on all of Plaintiffs' claims based on Plaintiffs' inability to prove specific medical causation; (2) on all of Plaintiffs' inadequate warning claims; and (3) on all of Plaintiffs' claims for punitive damages.

Plaintiffs filed responses to the Motions for Summary Judgment. In their Responses, Plaintiffs support their arguments with references to the "Declaration of John J. Vecchione, Esq. In Support of Plaintiffs' Opposition to Defendant's Motions to exclude Plaintiffs' Experts and for Summary Judgment in the *D'Agnese* Case." (Doc. 36) (the "Vecchione Declaration"). This Declaration is nine pages and the exhibits attached to it exceed 1,500 pages. Although this "Declaration" is not contemplated by the Court's local rules as responsive to a Motion for Summary Judgment,[2] it is in the Court's Record and, to the extent it was cited by Plaintiffs in their Responses to the Motions for Summary Judgment, the Court has considered it in ruling on the Motions for Summary Judgment.

Plaintiffs also filed "Plaintiffs' Responses to Counter-Statement of Undisputed Facts in Opposition to Defendant's Statement of Undisputed Facts in Support of Motion for Summary Judgment in the *D'Agnese* Case." (Doc. 126) ("Plaintiffs' Counter-Statement of Facts"). Plaintiffs' Counter-Statement of Facts is eighty-five pages and is in the Court's Record. This document is not referenced or cited to in any of Plaintiffs' Responses to the Motions for Summary Judgment.

Plaintiffs' Counter-Statement of Facts begins with the following "General Response," to Defendant's Motions for Summary Judgment:

> This case involves claims that Novartis' bisphosphonate drugs Aredia ® and Zometa® cause a new type of devastating jaw disease: bisphosphonate induced osteonecrosis of the jaw ("BIONJ"). Documents referenced herein are attached to the Declaration of John J. Vecchione in the *D'Agnese* case ("Vecchione *D'Agnese* Decl.") (Docket No. 36) filed contemporaneously herewith and are incorporated by reference. Plaintiffs also incorporate by reference the oppositions filed from time to time by the Plaintiffs' Steering

[2] *See* LRCiv 56.1 (solely contemplating a controverting statement of facts and additional facts that establish a genuine issue of material fact or otherwise preclude judgment and stating that a separate statement of facts "should include only those facts the Court needs to decide the motion.").

Committee ("PSC") in MDL-1760 in opposition to Novartis' various motions for summary judgment regarding causation and warnings, including **without limitation**: *Plaintiffs' Response to Novartis' Statement of Undisputed Facts in Support of Novartis' Motion for Summary Judgment on the Adequacy of Aredia® and Zometa® Warnings* filed on 7/1/2009 (DE 2616) and as corrected 7/13/2009 (DE 2639); *Plaintiffs' Opposition to Novartis' Motion for Summary Judgment on the Adequacy of Aredia® and Zometa® Warnings* filed on 7/1/2009 (DE 2614); *Plaintiffs' Memorandum In Opposition To Novartis' Motion For Summary Judgment Based On Failure Of General Causation Proof Under Daubert* filed on 7/2/2009 (DE 2633) and as corrected 7/3/2009 (DE 2635); and the Second Declaration of Robert Germany filed on 6/28/2009 (DE 2465). Plaintiffs also incorporate by reference the statements of fact in the other Valad & Vecchione cases where applicable. FN1.

> FN1 **For example**, Plaintiffs adopt the prior responses on whether Novartis' drugs cause ONJ and Novartis' asserted list of "risk factors". *See* Deposition of Wayne Ray, Ph.D., Vol. I, 172:13-17 (bisphosphonates only risk factor for ONJ); 174:4-7 (dental extractions only cause ONJ in bisphosphonate users); 219:13-220:11 (cancer not a risk factor); 268:19-269:15 (you take away the bisphosphonate you take away the risk) (Feb. 20, 2009) (attached to the Vecchione *D'Agnese* Decl. as Exhibit 32) *and* Deposition of Wayne Ray, Ph.D., Vol. II, 505:20-506:18 (corticosteroids not a true risk factor) (Feb. 21, 2009) (attached to the Vecchione *D'Agnese* Decl. as Exhibit 33).

Plaintiffs adopt by reference the Opposition Statement of Facts Filed by the PSC in Response to Motions for Summary Judgment or to exclude case wide experts as to all Wave I-A cases, Wave I-B cases, Wave I-C, and Wave II cases. Similarly, again for emphasis and **without limitation**, the Second Declaration of Robert Germany is explicitly incorporated herein.

(Doc. 126 at 2-3) (emphasis added).

Aside from the Vecchione Declaration, none of the other documents referenced are in this Court's Record. It is entirely unclear to the Court why Plaintiffs believe they may "incorporate by reference" numerous other documents that are not in this Court's Record in this case.[3] Plaintiffs appear to expect the Court to locate and then scour various other documents not in the Record and to attempt to determine why they are relevant to the issues in the D'Agnese case, and to guess at why they may apply to this case. There is no authority for this type of incorporation. The Court can see no other purpose to incorporating all other responses to other motions for summary judgment, oppositions to statements of facts in support of other motions for summary judgment, and other declarations filed in support of responses to summary judgment filed in other cases that are not before this Court, except to confuse the issues that are currently before this Court. This is completely unacceptable and has served no other purpose than to needlessly complicate the Court's ability to rule on the motions pending before it.

Further, this Court has previously informed Plaintiffs that such incorporation by reference is not permitted:

> Plaintiffs filed one Response to Defendant's *Daubert* motions regarding Dr. Marx, Dr. Fletcher, Dr. Ray, Dr. Skubitz, and Dr. Vogel. In that Response, Plaintiffs attempt to "incorporate by reference" "the entirety of the *Daubert* opposition briefs and all exhibits filed in [the MDL case] in the 'Wave I-A' cases, filed on September 1, 2010, in the 'Wave I-B' cases, filed on November 22, 2010 in the 'Wave I-C' cases, filed on June 20, 2011 in the 'Wave II' cases, filed on November 30, 2011 in the Wave 'III' cases filed on September 16, 2012 in the Wave 'IV' cases, and oppose [Defendant's] current motion to exclude these witnesses for those and the following reasons." (Doc. 104 at 2). Plaintiffs have not attached any of these "oppositions" to their

[3] According to Plaintiffs' own representations, they have attempted to incorporate by reference, *without limitation*, 2085 pages that are not in this Court's Record. (Doc. 169).

Response. Plaintiffs rely on Federal Rule of Civil Procedure 10(c) for this "incorporation by reference."

First, Federal Rule of Civil Procedure 10(c) does not apply to arguments in certain motions being incorporated by reference into new motions. Rather, Federal Rule of Civil Procedure 10(c) allows statements in *pleadings* to be adopted by reference in any other pleadings or motions. *See* Fed.R.Civ.P. 10(c); Fed.R.Civ.P. 7(a) (defining pleadings as a complaint, answer to a complaint, answer to a counterclaim designated as a counterclaim, an answer to a crossclaim, a third-party complaint, an answer to a third-party complaint and a reply to an answer).

Second, this attempt to incorporate various documents by reference that include arguments related and unrelated to the current issues before the Court circumvents this Court's local rules governing page limits.

Finally, this Court is not going to dig through various documents (copies of which have not even been provided by Plaintiffs) in order to determine what arguments in those other oppositions Plaintiffs believe may or may not be relevant to the issues *currently* before the Court. It is Plaintiffs obligation to oppose Defendant's arguments and not this Court's obligation to attempt to ascertain what arguments from other motions Plaintiffs may be trying to make again. *See Orr v. Bank of America,* 285 F.3d 764, 775 (9th Cir. 2002) (internal quotation omitted) ("Judges need not paw over the files without assistance from the parties.")); *Indep. Towers of Wash. v. Washington,* 350 F.3d 925, 929 (9th Cir. 2003) ("[J]udges are not like pigs, hunting for truffles buried in briefs.'") (citation omitted).

If Plaintiffs required a page extension to respond to Defendant's argument on the *current* Motions pending before the Court, they could have either filed separate responses to each *Daubert* Motion or could have requested a page extension from the Court. Plaintiffs chose to do neither and erroneously relied on Federal Rule of Civil Procedure 10(c) to incorporate arguments in various other oppositions that are not in this Court's record by reference into the current

> Response.
>
> > Accordingly, the Court has not considered any of the oppositions that Plaintiffs attempted to "incorporate by reference" that were filed in the MDL.

(Doc. 139 at 21-22 n.4).

While the Court recognizes that the above-quoted Order was filed after Plaintiffs' filed their Counter-Statement of Facts, in the over six months since the Court issued that Order, Plaintiffs made no attempt to supplement the Record or clarify their filings. As the Court has previously stated, it is Plaintiffs obligation to oppose Defendant's arguments and not this Court's obligation to attempt to ascertain what arguments from other motions in other cases Plaintiffs may be trying to reiterate in this case. *See Orr v. Bank of America,* 285 F.3d 764, 775 (9th Cir. 2002) (internal quotation omitted) ("Judges need not paw over the files without assistance from the parties.")); *Indep. Towers of Wash. v. Washington,* 350 F.3d 925, 929 (9th Cir. 2003) ("[J]udges are not like pigs, hunting for truffles buried in briefs.'") (citation omitted).

Accordingly, the Court has not considered any responses, statements of fact, or evidence that is not in its Record.

II. LEGAL STANDARD

Summary judgment is appropriate when "the movant shows that 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). "A party asserting that a fact cannot be or is genuinely disputed must support that assertion by . . . citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits, or declarations, stipulations . . . admissions, interrogatory answers, or other materials," or by "showing that materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." *Id.* at 56(c)(1)(A)&(B). Thus, summary judgment is mandated "against a party who fails

to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

Initially, the movant bears the burden of pointing out to the Court the basis for the motion and the elements of the causes of action upon which the non-movant will be unable to establish a genuine issue of material fact. *Id.* at 323. The burden then shifts to the non-movant to establish the existence of material fact. *Id.* The non-movant "must do more than simply show that there is some metaphysical doubt as to the material facts" by "com[ing] forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986) (quoting Fed. R. Civ. P. 56(e) (1963) (amended 2010)). A dispute about a fact is "genuine" if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In the summary judgment context, the Court construes all disputed facts in the light most favorable to the non-moving party. *Ellison v. Robertson*, 357 F.3d 1072, 1075 (9th Cir. 2004)

III. DEFENDANT'S MOTION FOR SUMMARY JUDGMENT ON INADEQUATE WARNINGS AND REMAINING CLAIMS (DOC. 112)

Defendant argues that the Court should grant summary judgment on all of Plaintiffs' claims because: (1) Defendant warned about the association between ONJ and Aredia® /Zometa® in 2003 when the first association between bisphosphonates and ONJ was discovered, (2) Mr. D'Agnese was warned of the risk of ONJ and signed a written informed consent to continue receiving Zometa® despite being informed of the risk; and (3) Plaintiffs cannot prove proximate cause because Mr. D'Agnese's prescribing oncologist still prescribes Zometa® to myeloma patients like Mr. D'Agnese in the same manner, dosage, and frequency as he prescribed Zometa® to Mr. D'Agnese.

A. FACTUAL BACKGROUND

1. Mr. D'Agnese's Prescriptions

In this case, Mr. D'Agnese began taking Aredia® in 1996. (Doc. 116 at ¶ 15; Doc. 126 at ¶ 15). On August 22, 2002, Mr. D'Agnese's former oncologist, Dr. Curley, noted that Mr. D'Agnese continued using Aredia® because of "the known incidence of increased bone events in patients who are not taking Aredia® with multiple myeloma." (Doc. 116 at ¶ 16; Doc. 126 at ¶ 16; Doc. 117-5).[4] Dr. Olshan, Mr. D'Agnese's current oncologist, first saw Mr. D'Agnese on May 16, 2002 and, at that time, switched Mr. D'Agnese from Aredia® to Zometa® therapy. (Doc. 116 at ¶ 17; Doc. 126 at ¶ 17). Dr. Olshan performed an oral examination on Mr. D'Agnese on May 16, 2002. (Doc. 116 at ¶ 19 Doc. 126 at ¶ 19).

2. Defendant's Warnings

Prior to September 2003, Defendant did not provide any warnings regarding a connection between bisphosphonates and ONJ. In September 2003, NPC informed the FDA that it was revising the Adverse Reactions section of the Aredia® and Zometa® labeling to include the language that:

> 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

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[4] In their Counter-Statement of Facts, Plaintiffs frequently claim that many of Defendant's supported facts are "disputed." However, Plaintiffs frequently do not cite to any evidence supporting their contention that Defendant's facts are disputed. On summary judgment, a plaintiff must do more than simply claim that a fact is disputed. Rather, a plaintiff has the burden of coming forward with evidence from which a reasonable jury could return a verdict in their favor. *See, e.g.*, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986) (The non-movant "must do more than simply show that there is some metaphysical doubt as to the material facts" by "com[ing] forward with 'specific facts showing that there is a genuine issue for trial.'") (quoting Fed. R. Civ. P. 56(e) (1963) (amended 2010)). As such, to the extent that Defendant stated facts that were supported by evidence in the Record and Plaintiffs failed to dispute those facts with controverting *evidence*, the Court has accepted Defendant's facts as true.

> 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).

Doc. 116 at 104.

In February 2004, the Zometa® label was revised to include language that "Although casualty cannot be determined, it is prudent to avoid dental surgery as recovery may be prolonged." (Doc. 116 at ¶ 108). On September 24, 2004, the package insert for Zometa® was revised to include the following three paragraphs in the precautions section regarding the potential risk of ONJ:

> 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.
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> 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).
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> 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.

(Doc. 116 at ¶ 110).

On September 24, 2004, NPC sent a "Dear Doctor" letter to more than 17,200

hematologists, urologists, oral surgeons, and oncologists, based on the American Medical Association membership list notifying them of the label change. The letter alerted prescribing physicians to the change in the Zometa® label and reiterated its pertinent language including:

> Precautions: Osteonecrosis of the jaw (ONJ) has been reported in patients with cancer receiving treatment regiments including bisphosphonates . . . A dental examination with appropriate preventative history 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.

(Doc. 116 at ¶111).

3. Warnings about ONJ to Mr. D'Agnese and his Oncologist

On March 1, 2005, Dr. Olshan informed Mr. D'Agnese of potential side effects of Zometa®, including ONJ, and recommended that Mr. D'Agnese see his dentist every six months or sooner as needed. (Doc. 116 at ¶ 40). Mr. D'Agnese testified that he did not recall this conversation. (Doc. 126 at ¶ 40). Likewise, on March 1, 2005, Dr. Olshan presented Mr. D'Agnese with a written informed consent form disclosing that ONJ was a risk of continuing with Zometa® therapy. (Doc. 116 at ¶ 41, 43). Mr. D'Agnese signed the form. (Doc. 116 at ¶ 41). Mr. D'Agnese identified his signature on the form, but does not remember signing it. (Doc. 126 at ¶ 41). On December 16, 2005, Mr. D'Agnese made it clear that he wanted to continue receiving Zometa® therapy despite being informed of the risk of ONJ multiple times over the preceding months. (Doc. 116 at ¶ 49; Doc. 126 at ¶ 49). In 2005, Dr. Lines tentatively diagnosed Mr. D'Agnese with BRONJ. (Doc. 36-18 at 2).[5] Despite the risks, to this day, Dr. Olshan continues to

[5] In their Motion for Summary Judgment on Causation, Defendant disputes that Mr. D'Agnese ever had BIONJ. However, for the purposes of the Court's ruling on Defendant's Motion for Summary Judgment on Inadequate Warnings, the Court assumes that Mr. D'Agnese had BIONJ in 2005.

prescribe Zometa® to multiple myeloma patients. (Doc. 116 at ¶¶ 22, 32). In 2010, Dr. Olshan encouraged Mr. D'Agnese to restart Zometa® at the same dosage and frequency that he was on previously. (Doc. 116 at ¶ 56).

Defendant asserts that summary judgment is appropriate on Plaintiffs' claims for strict liability (Count I), negligence—negligent manufacture (Count II), negligence—failure to warn (Count III), and breach of implied warranty (Count V) because each of these claims is premised on Defendant's alleged failure to warn Mr. D'Agnese about the risks of using Aredia® and Zometa®. (Doc. 113 n.1). In Response, Plaintiffs do not address this argument and, thus, do not dispute Defendant's contention that Counts I, II, III, and V of Plaintiffs' Complaint are premised on Defendant's alleged failure to warn.[6]

"To establish a prima facie case of products liability, at a minimum, the plaintiff must show that the product is in a defective condition and unreasonably dangerous, the defective condition [existed] at the time the product left the defendant's control, and the defective condition is the proximate cause of the plaintiff's injury." *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 184 (D. Ariz. 1999) (citing *Gosewisch v. American Honda Motor*

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[6] During oral argument, Plaintiffs' counsel argued for the first time that Pennsylvania law, and not Arizona law, should apply to issues regarding the adequacy of the warnings regarding the prescriptions of Aredia® to Mr. D'Agnese. Aside from this conclusory assertion at oral argument, Plaintiffs did not raise this issue in their summary judgment briefing, and did not raise it in the over six months since briefing was complete until oral argument. As such, the Court has no case law or facts supporting this argument and Defendant has not been given an adequate opportunity to respond to the argument. Moreover, although Defendant relied entirely on Arizona law in moving for summary judgment, and cited to various Arizona cases to support its position, Plaintiff raised no opposition to this reliance in its responsive brief. Because this argument was raised after full briefing on the motions for summary judgment and, in a conclusory statement at oral argument, the Court will not consider it. *See Vigilant Ins. v. Sunbeam Corp.*, 231 F.R.D. 582, 593 (D. Ariz. 2005) (citing *Holman v. Indiana*, 211 F.3d 399, 406 (7th Cir. 2000)); *see also In re Pacific Pictures Corp.*, 679 F.3d 1121, 1130 (9th Cir. 2012). The Court further notes that Plaintiffs' counsel frequently made arguments at oral argument and stated "this isn't in my papers either." It is entirely unclear to the Court why Plaintiffs' counsel views oral argument as a time to supplement fully briefed motions, but, as discussed above, such supplementation is not appropriate.

Co., Inc., 737 P.2d 376, 379 (1987) (*superseded on other grounds by* Ariz. Rev. Stat. §12-2506)). "Failure to prove any one of these elements is fatal." *Id.* (citing *Gosewisch*, 191 F.R.D. at 379).

"Three types of defects can result in an unreasonably dangerous product: (1) design defects,[7] (2) manufacturing defects, and (3) informational defects encompassing instructions and warnings." *Id.* (citing *Gosewisch*, 191 F.R.D. at 379)).

In this case, Defendant argues that Plaintiffs have failed to establish a genuine issue of material fact: (1) that Aredia® and Zometa® were unreasonably dangerous because Plaintiffs cannot show that Defendant's warnings were inadequate under either strict liability or negligence theories and (2) that, even if the warnings were inadequate, that such inadequate warnings were the proximate cause of Mr. D'Agnese's injury. The Court will address each of these arguments in turn.

B. LEGAL STANDARD AND ANALYSIS

Under Arizona law, when a negligence claim is based on a failure-to-warn theory, the plaintiff is required to "prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." *Powers v. Taser Int'l, Inc.*, 174 P.3d 777, 783 (Ariz. Ct. App. 2007) (internal citation omitted). Unlike a negligence claim based on a failure-to-warn theory, a strict liability claim based on a failure-to-warn theory is "not concerned with the standard of due care or the reasonableness of a manufacturer's conduct." *Id.* (internal citation omitted). Rather, under Arizona law, when a strict liability claim is based on a failure-to-warn theory, the plaintiff is required to prove:

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[7] "A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients." *Gebhardt*, 191 F.R.D. at 185 (quoting Restatement (Third) Torts § 6(c)).

> that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. *Thus, in strict liability, as opposed to negligence, the reasonableness of defendant's failure to warn is immaterial*.

Id. (emphasis in original) (internal citation omitted).

Further, under Arizona law, "the theory of liability under implied warranty has been merged into the doctrine of strict liability," and, thus, Plaintiffs' breach of implied warranty claim has merged with their strict liability claim. *Scheller v. Wilson Certified Foods, Inc.*, 559 P.2d 1074, 1076 (Ariz. Ct. App. 1976); *Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 185 (D. Ariz. 1999).

Defendant argues that it cannot be liable under strict liability or negligence theories of failure to warn because Defendant specifically warned about the association between ONJ and Aredia® /Zometa® in 2003 as soon as a possible association was first discovered and a duty to provide such a warning even arguably arose.

Defendant next argues that, even if its warnings were inadequate at any time, Plaintiffs cannot carry their burden of proving proximate cause in this case because Mr. D'Agnese's oncologist, Dr. Olshan, warned him of the risk of ONJ while obtaining his written informed consent to continue receiving Zometa® despite that risk, and Mr. D'Agnese expressly accepted that risk in order to receive the benefits of Zometa®.

"Ordinarily, what constitutes the proximate cause of any injury is a question of fact. However, the jury is not entitled to make a decision absent a proper evidentiary foundation." *Gebhardt*, 191 F.R.D. at 185 (citing *Gosewisch*, 737 P.2d at 380).

To prove causation, it is Plaintiffs burden to present evidence that, if Defendant had issued a proper warning, Mr. D'Agnese would not have taken Aredia® or Zometa®. *Golonka*, 65 P.3d at 955-966; *see Southwest Pet Products Inc. v. Koch Industries, Inc.*, 273 F.Supp.2d 1041, 1060 (D. Ariz. 2003) (stating that, to make out a prima facie case of

strict products liability based on an information defect, plaintiff must establish that defendant's failure to warn caused Plaintiff's injuries). In Arizona, there is heeding presumption used in strict liability information defect cases that allows "the fact-finder to presume that the person injured by product use would have heeded an adequate warning, if given." *Golonka*, 65 P.3d at 967. However, the heeding presumption is rebuttable and, if the manufacturer introduces evidence that would permit reasonable minds to conclude that the injured party would not have heeded an adequate warning, the presumption is destroyed as a matter of law and the existence or non-existence of the presumed fact must be determined as if the presumption had never operated in the case. *Id.* at 971-72.

Defendant further argues that Plaintiffs are unable to carry their burden of establishing proximate cause because Mr. D'Agnese's prescribing oncologist still prescribes Zometa® to myeloma patients like Mr. D'Agnese today in the same manner and dosage and frequency as he prescribed it to Mr. D'Agnese.

Arizona courts follow the learned intermediary doctrine. *Piper v. Bear Med. Sys., Inc.*, 883 P.2d 407, 415 (Ariz. Ct. App. 1993). Under the learned intermediary doctrine, a manufacturer of a prescription drug has a duty to warn physicians, and not consumers, of the risks associated with the drug. *Piper*, 883 P.2d at 415 n. 3. To succeed on a failure-to-warn claim, a plaintiff must establish causation by submitting evidence that the medical outcome would have been different if different warnings had been provided to the physician, i.e., that the provider would not have recommended the product, or that the patient would not have suffered the injuries. *See Gebhardt v. Mentor Corp.*, 191 F.R.D. 180, 184–5 (D. Ariz. 1999). When a prescriber is aware of the risks associated with a prescription medication and chooses to prescribe the medication in spite of these risks, or would not have modified the decision even if alternate warnings had been provided, the plaintiff has failed to establish that the manufacturer's failure to warn was the proximate cause of the plaintiff's alleged injury. *See id.*; *Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) ("a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the

prescribing physician.") It is Plaintiffs' burden to establish proof that stronger warnings would have changed Mr. D'Agnese's medical treatment. *Motus*, 358 F.3d at 661.

Defendant argues that Plaintiffs cannot prove that the an inadequate warning was the proximate cause of Mr. D'Agnese's injury in this case because they have failed to provide any testimony that, if different warnings had been provided to Plaintiffs' prescribing physicians—namely Dr. Curley and Dr. Olshan—the providers would not have recommended Aredia® and/or Zometa® or that Mr. D'Agnese would not have suffered his injuries. The Court agrees that Plaintiffs have failed to establish proof that stronger warnings would have changed Mr. D'Agnese's medical treatment in this case.

First, Plaintiffs have failed to establish a genuine issue of material fact that Defendant's warnings were inadequate at the time Dr. Curley first proscribed Aredia® to Mr. D'Agnese in 1996. Plaintiffs argue that Defendant knew that ONJ was caused by bisphosphonates in 1996 because (1) in 1983, Dr. Jack Gotcher and Dr. W.S.S. Jee published an article explaining an experiment where rats were exposed to a bisphosphonate drug called clodronate and their findings that several of the rats had devitalized bone protruding in the oral cavities of rats treated with clodronate and (2) in 2005, after reports of links between ONJ and bisphosphonates, Defendant discovered what may have been six cases of ONJ in their original clinical trials of Aredia® in 1991.

Plaintiffs have not pointed to any evidence, including any testimony, suggesting that based on one study and six possible cases of ONJ in a clinical trial, Defendant's actions fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about. Likewise, Plaintiffs have not pointed to any evidence or testimony that, in light of this article and six possible cases of ONJ in the clinical trial, ONJ was a knowable risk of using Aredia® in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Although Plaintiffs argue that Defendant's original clinical trials and testing was insufficient, Plaintiffs do not point to any evidence of this and, as such, it appears to be mere speculation. Moreover, Arizona Courts are

clear that claims based on inadequate warnings cannot be based on the information now available regarding connections between ONJ and bisphosphonates, but rather must be based on what was knowable at the time a warning should have allegedly been given. *See Taser*, 174 P.3d at 783 ("it is our view that employing the hindsight test in warning defect cases would be tantamount to imposed a duty on manufacturers to warn of unknowable dangers."). Accordingly, based on the evidence presented by Plaintiffs, no reasonable jury could find that Defendant's warnings were inadequate when Aredia® was first prescribed to Mr. D'Agnese in 1996.

Even if Plaintiffs produced sufficient evidence upon which a reasonable person could conclude that the warnings were inadequate in 1996, Plaintiffs' claims also fail because Plaintiffs have offered no evidence that warnings to Dr. Curley would have changed his decision to prescribe Aredia® to Mr. D'Agnese in 1996. Although Plaintiffs appear to suggest that it is Defendant's burden to demonstrate that Dr. Curley's prescription decisions would have been different, it is Plaintiffs' burden to demonstrate proximate cause. *See, e.g.*, *Motus*, 358 F.3d at 661 (finding that summary judgment was appropriate where plaintiff failed to establish proof that stronger warnings would have changed the medical treatment provided or that such warnings would have averted the injury). Although Plaintiffs may be attempting[8] to rely on the heeding presumption to prove that, if Dr. Curley had adequate warnings from Defendant, his decision to prescribe ONJ would have been different,[9] Defendant has presented sufficient evidence to

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[8] Although Defendant argued that the heeding presumption is inapplicable in this case, Plaintiffs did not address this argument in their responsive brief or otherwise argue in their responsive brief that the heeding presumption would apply.

[9] Because Arizona follows the learned intermediary doctrine, Plaintiffs must show that "a prescribing physician given an adequate warning would have 'heeded' the warning by incorporating that warning into his risk-benefit analysis in deciding whether to prescribe a given drug." *See Ingram v. Novartis Pharmaceuticals Corp.*, 888 F.Supp.2d 1241, 1244 (D. Okla. 2012) (internal citation omitted); *Gebhardt*, 191 F.R.D. at 184–185 (plaintiff must establish causation by submitting evidence that the medical outcome would have been different if different warnings had been provided to the

overcome the heeding presumption in this case. Specifically, Defendant has presented evidence that, in 2010, Dr. Olshan recommended that Mr. D'Agnese restart Zometa® at the same dose and frequency as his original dose, years after Mr. D'Agnese developed ONJ and Dr. Olshan continues to proscribe Zometa® to his patients. Moreover, even after being warned of the possible risk of ONJ, Mr. D'Agnese continued to take Zometa®.[10] This would permit reasonable minds to conclude that Mr. D'Agnese's original prescribing doctor would have nonetheless prescribed Aredia® to Mr. D'Agnese and/or that Mr. D'Agnese's ONJ would not have been averted. Thus, as a matter of law, the heeding presumption does not apply in this case. When the heeding presumption no longer applies, Plaintiffs must present evidence that stronger warnings would have changed Mr. D'Agnese's medical treatment or averted his ONJ. Plaintiffs have failed to present any evidence that Defendant's allegedly inadequate warnings had any influence on Dr. Curley's decisions to prescribe Aredia® to Mr. D'Agnese.

Accordingly, on the evidence before the Court, no reasonable juror could find that Mr. D'Agnese's ONJ was caused by Defendant's allegedly inadequate warnings. This conclusion is based on the absence of any evidence that Defendant's warnings were inadequate at the time that different warnings would have prevented Mr. D'Agnese from developing ONJ, that different warnings would have changed the prescribing practices of Mr. D'Agnese's prescribing doctors or that different warnings would have prevented Mr. D'Agnese's injury, and Plaintiffs' failure to point to specific summary judgment evidence to create a genuine issue of fact as to whether Defendant's failure to warn was the proximate cause of Mr. D'Agnese's injury. As such, Defendant is entitled to summary judgment on Plaintiffs' claims for strict liability (Count I), negligence—negligent manufacture (Count II), negligence—failure to warn (Count III), and breach of implied warranty (Count V).

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physician).

[10] Although Mr. D'Agnese does not remember signing the informed consent form provided by Dr. Olshan, Mr. D'Agnese does not dispute that he did sign the form.

Defendant further argues that summary judgment must be granted on Plaintiffs' claim for breach of express warranty (Count IV) because Plaintiffs have not provided any evidence that Defendant ever made any express warranty to Mr. D'Agnese, or that Mr. D'Agnese has ever spoken with anyone associated with Defendant or received any written materials from Defendant prior to or during his use of either Aredia® or Zometa®. Under Arizona law, "[a]n express warranty claim requires a showing that the seller made an affirmation of fact or promise that became the basis of the bargain." *Mills v. Bristol-Myers Squibb Co.*, No. CV 11-968-PHX-FJM, 2011 WL 3566131, at *3 n.3 (D. Ariz. Aug. 12, 2011). In Response to Defendant's Motion for Summary Judgment, Plaintiffs did not address Defendant's argument that Plaintiffs have not provided any evidence of breach of an express warranty and did not otherwise provide evidence indicating the presence of an express warranty in this case. Accordingly, Plaintiffs have failed to establish the existence of a material fact on their breach of express warranty claim and, thus, summary judgment is granted in favor of Defendant on Plaintiffs' express warranty claim (Count IV).

Finally, Defendant argues that it is entitled to summary judgment on Plaintiffs' claim for loss of consortium (Count VI) because Plaintiffs have failed to establish a genuine issue of material fact on any of its underlying tort claims. Indeed, because a claim for loss of consortium is derivative of the underlying tort, "all elements of the underlying cause must be proven before the claim can exist." *Barnes v. Outlaw*, 964 P.2d 484, 487 (Ariz. 1998). Accordingly, because Defendant is entitled to summary judgment on Plaintiffs' tort claims, Defendant is also entitled to summary judgment on Plaintiffs' claim for loss of consortium (Count VI).

Moreover, because the Court has granted Defendant's Motion for Summary Judgment on Inadequate Warnings and Remaining Claims, the Court need not address the remaining two motions for summary judgment and those motions are denied as moot.

IV. CONCLUSION

Based on the foregoing,

IT IS ORDERED that Defendant's Motion for Summary Judgment on Inadequate Warnings and Remaining Claims (Doc. 112) is granted. The Clerk of the Court shall enter judgment in favor of Defendant accordingly.

IT IS FURTHER ORDERED that Defendant's Motion for Summary Judgment on Specific Medical Causation (Doc. 110) is denied as moot.

IT IS FURTHER ORDERED that Defendant's Motion for Summary Judgment on Plaintiffs' Punitive Damages Claim (Doc. 114) is denied as moot.

Dated this 2nd day of July, 2013.

James A. Teilborg
Senior United States District Judge