SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.
JUDGE

MIDDLESEX COUNTY COURT HOUSE
P.O. Box 964
NEW BRUNSWICK, NEW JERSEY 08903-0964

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Memorandum of Decision on Defendant's Motion for Summary Judgment on Plaintiffs' Claims and Defendant's Motion to Preclude Punitive Damages

BESSEMER V. NOVARTIS PHARMACEUTICALS CORP., Docket No. MID-L-1835-08
(In re: Zometa/Aredia Litigation, Case No. 278)

For Defendant: Joe Hollingsworth, Esq. Hollingsworth LLP

For Plaintiffs: John Vecchione, Valad & Vecchione, PLLC

Dated: April 30, 2010

Defendant Novartis Pharmaceuticals Corporation ("NPC" or "Defendant") moves for summary judgment as to all of the claims alleged by Plaintiffs Jane and Allen Bessemer ("Plaintiffs") in their amended complaint. The court has considered the written submissions and the arguments of counsel regarding Defendant's motion for summary judgment and motion to preclude Plaintiffs' punitive damages claim. The following memorandum sets forth the court's disposition of NPC's motions.

Statement of Material Facts

Defendant manufactures and sells Aredia® and Zometa® ("Aredia/Zometa®") – FDA-approved[1] intravenous ("IV") bisphosphonates administered to patients who have hypercalecemia of malignancy, multiple myeloma, or cancer that has metastasized to the bones. Defendant's Statement of Undisputed Material Facts ("Def. SUF") at ¶¶ 1-7. For patients with bone-metastasized cancer, such as Plaintiff Jane Bessemer ("Ms. Bessemer"), Aredia/Zometa® is prescribed to reduce the risk of skeletal-related events ("SREs"), such as fractures and spinal degeneration, and to alleviate bone pain. Id. at ¶¶ 1, 8, 21. The initial labels for both Aredia® and Zometa® were approved by the United States Food and Drug Administration ("FDA"). Id. at ¶ 10.

On December 6, 2002, NPC received a report concerning the development of ONJ in a patient receiving its IV bisphosphonate drug. Id. at ¶ 87.[2] Six days later, on December 12, 2002, NPC submitted this adverse event report to the FDA. Id. at ¶ 89. On December 11, 2002, NPC received additional information involving twenty-six patients treated with IV bisphosphonates, who developed painful oral lesions. Id. at ¶ 90; Pl. SOF Opp. SJ Pun. at ¶ 21.

Over a month later, on January 13, 2002, NPC asked a third-party not affiliated with the company, Dr. Ruggiero, to provide clinical information on the twenty-six patients who developed oral lesions while receiving IV bisphosphonates. Def. SUF at ¶ 92. As of January 22, 2003, Dr. Ruggiero had gathered only enough information for NPC to complete one adverse

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[1] In 1991, Aredia® was approved in the United States solely for the treatment of hypercalcemia of malignancy ("HCM"). Plaintiffs' Statement of Fact in Opposition to Novartis's Motion for Summary Judgment to Preclude Punitive Damages ("Pl. SOF Opp. SJ Pun.") at ¶ 3. In 1996, Aredia® was approved for other uses, including treatment of osteolytic bone metastases associated with breast cancer. Id. at ¶ 5. Zometa® was approved in August 2001 for HCM and subsequently, in February 2002, was approved for other uses, including treatment of bone metastases associated with myeloma, breast cancer, prostate cancer, and other solid tumor cancers. Id. at ¶ 7.

[2] According to Plaintiffs, Defendant received its first notice of an association between bisphosphonates and osteonecrosis in April 2002, based upon an inquiry from Dr. Salvatore Ruggiero of Long Island Jewish Hospital ("Dr. Ruggiero"). Pl. SOF Opp. SJ Pun. at ¶ 20.

report for submission to the FDA. Id. at ¶¶ 93-94. However, NPC informed the FDA of the existence of the twenty-five other possible reports at that time. Id. at ¶ 95. NPC reviewed its preclinical studies and FDA submissions to determine whether osteonecrosis occurred during the preclinical research stage of Aredia/Zometa®. Id. at ¶ 99. According to NPC's review of its preclinical studies, there was only a single report of osteonecrosis of the rib and femur of a dog who received a dose of a bisphosphonate equivalent to eight times the approved human dose of Aredia/Zometa®. Ibid.

NPC claims it learned of thirty-six additional cases of ONJ in June 2003, id. at ¶ 103, and the first case report about ONJ in bisphosphonate-users was published in September 2003, id. at ¶ 98. On the other hand, Plaintiffs claim there were earlier case reports published in a textbook, a fact made known to NPC in March 2003. See Plaintiff's Response to Defendant NPC's Statement of Material Facts in Support of Its Motion for Summary Judgment ("Pl. Resp. to Def. SUF") at ¶¶ 98, 103.

On September 26, 2003, NPC added the following language in the "Adverse Reactions" section of the Aredia/Zometa® label:

> Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. [ONJ] has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa or other bisphosphonates, to concomitant drugs or other therapies (e.g., chemotherapy, radiotherapy, corticosteroid), to patient's underlying disease, or to other co-morbid risk factors (e.g., anemia, infection, pre-existing oral disease).
>
> [Def. SUF at ¶ 113; Pl. SOF Opp. SJ Pun. at ¶ 35.]

This label change was made through a "CBE 0," without prompting from the FDA. Def. SUF at ¶ 112; see 21 C.F.R. § 314.70(c)(6)(iii)(A) (FDA approval is not required where the manufacturer seeks to "add or strengthen a contraindication, warning, precaution, or adverse reaction" to the label); see also McDarby v. Merck & Co., Inc., 401 N.J. Super. 10, 58 (App.

Div. 2008) (quoting In Re Vioxx Prods. Liab. Litig., 501 F. Supp. 2d 776, 782-83 (E.D.La. 2007)). The effective date of NPC's label change was November 2003. Pl. SOF Opp. SJ Pun. at ¶ 36. NPC's label change was accepted by the FDA as submitted. Def. SUF at ¶ 115.

In February 2004, at the request of the FDA, NPC revised the "Post-Marketing Experience" section of the Zometa® label to also include the following language: "Although causality cannot be determined, it is prudent to avoid dental surgery as recovery may be prolonged." Id. at ¶ 121. This revision was made pursuant to an FDA supplemental New Drug Application ("sNDA"), Def. SUF at ¶ 122, and was approved by the FDA on February 27, 2004, ibid.; Pl. SOF Opp. SJ Pun. at ¶ 40.

In September 2007, NPC removed language in the Zometa® label regarding the "well-documented risk factors" for ONJ. The new label stated:

> Cases of osteonecrosis (primarily involving the jaws) have been reported predominantly in cancer patients treated with intravenous bisphosphonates including Zometa. Many of these patients were also receiving chemotherapy and corticosteroids which may be a risk factor for ONJ.
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> [Pl. SOF Opp. SJ Pun. at ¶ 59.][3]

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[3] The "Warnings and Precautions" section of the Zometa® label currently reads as follows:

Osteonecrosis of the jaw (ONJ) has been reported predominantly in cancer patients treated with intravenous bisphosphonates, including Zometa. Many of these patients were also receiving chemotherapy and corticosteroids which may be risk factors for ONJ. Postmarketing experience and the literature suggest a greater frequency of reports of ONJ based on tumor type (advanced breast cancer, multiple myeloma), and dental status (dental extraction, periodontal disease, local trauma including poorly fitting dentures). Many reports of ONJ involved patients with signs of local infection including osteomyelitis.

Cancer patients should maintain good oral hygiene and should have a dental examination with preventive dentistry prior to treatment with bisphosphonates.

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 [*see Adverse Reactions (6.2)*].

[Current Zometa® Prescribing Information Label (as of April 30, 2010), available at http://www.pharma.us.novartis.com/product/pi/pdf/Zometa.pdf.]

Ms. Bessemer was diagnosed with breast cancer in March 1991. Def. SUF at ¶ 11. According to Ms. Bessemer's oncologist, Dr. David Sharon ("Dr. Sharon"), by April 1997 Ms. Bessemer had stage four breast cancer that had metastasized to her bones. Id. at ¶ 12. Ms. Bessemer received chemotherapy in May and June 1997, from July to December 1997, and from late-May to late-July 2001. Id. at ¶¶ 14, 16, 23. She received radiation therapy from November 2001 through January 2002. Id. at ¶ 25.

In May 1999, Ms. Bessemer began treatment with Aredia® to reduce the risk of SREs. Id. at ¶¶ 21-22. Ms. Bessemer received her last dose of Aredia® on December 18, 2001 and switched to Zometa® the following month, receiving her first dose on January 15, 2002. Id. at ¶¶ 26-27.

There were no dental records presented for Ms. Bessemer prior to April 2000. Id. at ¶ 30. In April 2000, Ms. Bessemer visited her dentist, Dr. Edward Dooley ("Dr. Dooley"). Id. at ¶ 31. Ms. Bessemer's dental records from 2000 indicate she had a fixed partial denture spanning teeth # 18-20 (because tooth # 19 was missing), had periodontal disease, and had a history of teeth grinding. Id. at ¶¶ 31-33. On May 22, 2000, Dr. Dooley noted Ms. Bessemer's tooth # 31 "had severe caries, non-restorable as a posterior abutment," and he recommended extraction of tooth # 31. Id. at ¶ 38; Deposition of Dr. Edward Dooley ("Dooley Dep.") at 106:8-11, 105:10-11; Health Care Record of 5/22/00, attached as Exhibit 18 to the Certification of Charles Falletta, Esq. ("Falletta Cert.").] On June 2, 2000, tooth # 31 was extracted by Dr. John Feeney ("Dr. Feeney"), an oral surgeon. Def. SUF at ¶ 39.[4] In December 2000, Ms. Bessemer had a root

[4] Plaintiffs' specific causation expert, Dr. Richard Kraut ("Dr. Kraut"), testified Ms. Bessemer's ONJ stemmed, in part, from the extraction of tooth #31 in June 2000. Def. SUF at ¶ 41.

canal on tooth # 20 and a removal of the top of tooth # 18. Id. at ¶ 42. On February 19, 2001, Ms. Bessemer had tooth # 18 extracted. Id. at ¶ 43.[5]

On August 24, 2001, Ms. Bessemer had an infection of gum in the area where tooth # 31 was extracted. Id. at ¶ 45.[6] A biopsy of Ms. Bessemer's jaw bone on September 4, 2001 indicated she had neerotic or dead bone in her jaw. Id. at ¶ 51.[7] Later, in May 2004, Ms. Bessemer's oral surgeon, Dr. Ray Fonseca ("Dr. Fonseca"), included bisphosphonate-related ONJ ("BRONJ") in his differential diagnosis of Ms. Bessemer condition as Dr. Fonseca first learned of BRONJ around that time. Id. at ¶ 67. However, Dr. Fonseca did not rule out osteomyelitis as a cause of Ms. Bessemer's ONJ. Id. at ¶ 68.

Upon learning of the alleged causal association between Aredia/Zometa® and ONJ, Dr. Sharon discontinued Ms. Bessemer's Zometa® treatment on May 20, 2004. Def. SUF at ¶ 69. Ms. Bessemer received her last dose on April 22, 2004. Id. at ¶ 70. On June 13, 2005, Mrs. Bessemer's right posterior mandible was replaced with a titanium plate. Id. at ¶ 72.

In opposition to NPC's motion, Plaintiffs allege several significant "facts" that preclude judgment as a matter of law. Plaintiffs offer evidence that NPC knew or should have known of the risk of ONJ associated with Aredia/Zometa® as early as 1986. Pl. SOF Opp. SJ Pun. at ¶¶ 11-12. Plaintiffs explain that, in 1986, NPC's head of preclinical studies for Zometa® reviewed and retained a 1981 article allegedly showing an association between bisphosphonates and osteonecrosis. Ibid.; see Deposition of Jonathan Green M.D. ("Green Dep.") at 126:20-127:15. Plaintiffs also claim NPC should have known of the risk of ONJ with bisphosphonates based upon

[5] Ms. Bessemer did not develop ONJ in the area where tooth # 18 was extracted. See Def. SUF at ¶ 44.

[6] In April 2002, Ms. Bessemer also had tooth # 32 extracted, and the area healed without infection. Def. SUF at ¶¶ 57-59.

[7] The parties dispute whether Ms. Bessemer, in fact, had ONJ or another condition – osteomyelitis – at this time. See Pl. Resp. to Def. SUF at ¶¶ 48-50, 52-55.

various diseases that were known for decades, and that have similar biological mechanisms to bisphosphonates. See Pl. SOF Opp. SJ Pun. at ¶¶ 9-10. Plaintiffs further allege that ONJ cases appeared in the Aredia/Zometa® clinical trials but Defendant failed to conduct oral exams as part of its clinical trial protocols. Id. at ¶¶ 13-15. Plaintiffs also point to articles about a condition called "phossy jaw" – a disease resembling ONJ allegedly suffered by 19th century match factory workers. Id. at ¶¶ 16-19.

Summary Judgment Standard

In deciding a motion for summary judgment, the court must determine whether there is a genuine issue of a material fact. In analyzing a summary judgment motion, the court must consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational fact-finder to resolve the alleged disputed issue in favor of the non-moving party. Brill v. Guardian Life Insurance Co., 142 N.J. 520 (1995). A moving party is entitled to summary judgment "if the pleadings, depositions, and the admissions on file, together with an affidavit, if any, show palpably that there is no genuine issue as to judgment or order as a matter of law." R. 4:46-2; Judson v. People's Bank and Trust Co. of Westfield, 17 N.J. 67, 73, 75 (1954).

Legal Analysis of Plaintiffs' Claims

A. Failure to Warn under the New Jersey Products Liability Act ("PLA")

Plaintiffs allege Aredia/Zometa® is responsible for a form of ONJ specifically caused by bisphosphonate use, known as "bisphosphonate induced or related ONJ" ("BRONJ"). Plaintiffs add NPC failed to provide any information about ONJ or BRONJ for most of the five-year period that Ms. Bessemer was taking Aredia/Zometa®, from May 1999 to April 2004, and that the information eventually placed on the label during this time period was inadequate. Plaintiffs

accurately note the absence of information about ONJ in the "Warnings" section of the Aredia/Zometa® label at any time. Plaintiffs also allege Defendant violated a duty by failing to inform the dental community of the risk of ONJ, suggesting that Defendant went so far as to impede the dental community's knowledge of the risk of ONJ.

Plaintiffs assert Defendant had reason to know about BRONJ by the 1990's, but failed to investigate it and tried to conceal the risk associated with Aredia/Zometa® once the condition was brought to its attention. Finally, Plaintiffs allege Defendant advertised Zometa® directly to Ms. Bessemer and, therefore, NPC is not entitled to the learned intermediary doctrine defense in this case.

Defendant raises three main points in support of summary judgment as to Plaintiffs' failure-to-warn claim. First, NPC asserts the FDA-approved warnings were legally adequate. Second, Defendant contends Plaintiffs cannot prove that NPC's alleged failure to warn was the proximate cause of Ms. Bessemer's ONJ. Third, NPC maintains Plaintiffs cannot prove that Ms. Bessemer's use of Aredia/Zometa® was the medical cause of her ONJ.

1. The PLA

Under the New Jersey Products Liability Act, N.J.S.A § 2A:58C-1 et seq. (2010) ("PLA"):

> [a] manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.
>
> [N.J.S.A. § 2A:58C-2.]

With respect to failure to warn claims, generally, the PLA explains:

> [i]n any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction.
>
> [N.J.S.A. § 2A:58C-4.]

2. Duty to Warn

Defendant correctly notes a pharmaceutical manufacturer has no duty to warn of risks that were unknown or not scientifically knowable at a particular time. Defendant asserts Plaintiffs' failure-to-warn claim must fail because NPC did not know and could not have known about the risk of ONJ at any time relevant to Ms. Bessemer's claims in this case, including: (a) when she first began taking Aredia® in May 1999; (b) underwent the extraction in June 2000 that purportedly triggered her ONJ; (c) reported problems with her jaw consistent with ONJ in August 2001; or (d) was diagnosed with ONJ in September 2001. Defendant claims there were no reported cases of ONJ among Aredia/Zometa® users during these time periods (1991-2001). Def. SUF at ¶¶ 83-85. Defendant concludes its lack of actual or constructive knowledge regarding a product's harmful potential is fatal to a failure-to-warn claim requiring summary judgment as a matter of law.

Pursuant to New Jersey case law, a manufacturer has a duty to warn of all known adverse effects of a drug as soon as reasonably feasible based upon actual or constructive knowledge of a danger. See Feldman v. Lederle Lab., 97 N.J. 429, 434 (1984); see also In re Diet Drug Litig., 384 N.J. Super. 525, 534 (Law Div. 2005) ("manufacturers must provide consumers with warnings . . . about 'dangers of which they know or should have known on the basis of reasonably obtainable or available knowledge'") (quoting Feldman, supra, 97 N.J. at 434)). Thus, a manufacturer who knows or should have known of the danger of side effects of a product is not relieved of the duty to warn. See Feldman, supra, 97 N.J. at 434; In re Diet Drug, supra, 384 N.J. Super. at 534.

Plaintiffs offer evidenee that NPC should have known of the risk of ONJ assoeiated with Aredia/Zometa® as early as 1986 – before Ms. Bessemer began taking Aredia®, before she underwent a dental extraction, before she reported ONJ-related problems, and before she was diagnosed with ONJ. Pl. SOF Opp. SJ Pun. at ¶¶ 11-12. Plaintiffs explain that an article by authors Gotcher and Jee, appearing in 1981, should have placed NPC on notice of the potential risk of ONJ associated with Aredia/Zometa®. The 1981 article described an experiment testing a bisphosphonate drug, clodronate, on laboratory rats with periodontal disease (the "Gotcher & Jee article"). Ibid. While rats exposed to clodronate showed dead bone protruding in their oral cavities, the rats given the placebo had no dead jaw bone. Id. at ¶ 11. Plaintiffs claim the head of preclinical studies for NPC, Dr. Jonathan Green ("Dr. Green"), had the Gotcher & Jee artiele in his personal files as early as 1986, thus demonstrating Defendant's aetual knowledge of the risk of ONJ assoeiated with Aredia/Zometa®. Id. at ¶ 12; Green Dep. at 126:20-127:15. Significantly, Dr. Green was in charge of the preclinical studies leading to the approval of Zometa®. Pl. SOF Opp. SJ Pun. at ¶ 12; Green Dep. at 12:10-13:7.

Plaintiffs raise additional issues of material fact as to Defendant's constructive or actual knowledge about the risk of ONJ associated with bisphosphonates. See Pl. SOF Opp. SJ Pun. at ¶¶ 9-10 (noting the similarities in biological mechanisms between bisphosphonates and diseases that have been known for decades); id. at ¶¶ 13-15 (stating cases of ONJ appeared in the Aredia/Zometa® clinieal trials and Defendant failed to conduct oral exams as part of its clinical trial protocol); id. at 16-19 (discussing "phossy jaw" - a disease resembling ONJ allegedly suffered by 19th century match factory workers).

As to Defendant's claim that no one knew of the risk of ONJ associated with bisphosphonates before 2003, the court finds the Gotcher & Jee article, coupled with Dr. Green's

review and retention of that artiele in 1986, is sufficient evidence for a fact-finder to conclude NPC either knew or should have known of the potential risk of ONJ and bisphosphonate use prior to 2001. See Feldman, supra, 97 N.J. at 434; In re Diet Drug, supra, 384 N.J. Super. at 534. Therefore, because Plaintiffs have offered evidence of Defendant's alleged knowledge of ONJ prior to 2001, summary judgment is inappropriate.

3. Rebuttable Presumption of Adequacy

Defendant argues Plaintiffs cannot rebut the presumption of adequacy provided by the PLA because the FDA-approved warnings were in effect when Ms. Bessemer started taking Aredia® and Zometa®.

The PLA provides, "[i]f the warning or instruction given in connection with a drug . . . approved or prescribed by the federal [FDA,] . . . a rebuttable presumption shall arise that the warning or instruction is adequate." Ibid.; see also Perez v. Wyeth Laboratories Inc., 161 N.J. 1, 24 (1999) (a pharmaceutical company's compliance with FDA regulations provides "compelling evidence that a manufacturer satisfied its duty to warn the physician").[8]

However, the presumption of adequacy may be rebutted if a plaintiff presents evidence of either: (i) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects ("Perez/Rowe exception"), Perez, supra, 161 N.J. at 25; Rowe v. Hoffman-La Roche, Inc., 189 N.J. 615, 626 (2007), or (ii) substantial evidence of "manipulation of the post-market regulatory proeess," ("McDarby exception"), McDarby, supra, 401 N.J. Super. at 81. Here, Defendant relies

[8] As noted in N.J.S.A. § 2A:58C-4 "FDA approval: means agency approval pursuant to the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. 301, et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201, et seq.

on the initial pre-2003 label, along with its September 2003 and March 2004 updated labels, in support of the claimed presumption of adequacy.

a. The Perez/Rowe Exception

In Perez, the Supreme Court of New Jersey held that, "for all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive" of a failure to warn claim. Perez, supra, 161 N.J. at 25 ("[a]ny duty to warn physicians about prescription drug dangers is presumptively met by compliance with federal labeling"). Compliance with FDA regulations provides "compelling evidence that the manufacturer satisfied its duty to warn the physician." Id. at 24. This exception was reaffirmed by the Supreme Court in Rowe v. Hoffman-La Roche. Rowe, supra, 89 N.J. at 626.

Defendant claims Plaintiffs have not submitted any evidence showing that NPC deliberately concealed or failed to disclose knowledge about the risk of ONJ to the FDA once NPC became aware of adverse reports. Defendant notes NPC received its first adverse event report concerning ONJ on December 6, 2002. Def. SUF at ¶ 87.[9] Within six days of receiving its first adverse event report of ONJ, NPC submitted the information to the FDA. Id. at ¶ 89. NPC argues it complied with federal regulations on reporting of adverse events. See 21 C.F.R. § 314.80(c)(1)(i) (requiring drug manufacturers to "report each adverse drug experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information by the applicant"); see also 21 C.F.R. § 314.80(c)(ii)-(iii) (setting forth additional reporting requirements). NPC contends that,

[9] Defendant points out this was after Plaintiff: (a) was prescribed Aredia® in May 1999 and Zometa® in January 2002, (b) had the dental extraction that allegedly precipitated her injury in June 2000, and (c) was diagnosed with ONJ in September 2001. Def. SUF at ¶¶ 22, 27, 39, 41, 51.

upon learning of an additional twenty-six patients who developed painful oral lesions after being treated with bisphosphonates, it timely notified the FDA and began gathering information about those cases. Def. SUF at ¶¶ 90-95. NPC emphasizes that it changed the warning through a "CBE 0" without prompting from the FDA. Def. SUF at ¶ 112; see 21 C.F.R. § 314.70(c)(6)(iii)(A) (FDA approval is not required where the manufacturer seeks to "add or strengthen a contraindication, warning, precaution, or adverse reaction" to the label). The Aredia/Zometa® label change, as approved by the FDA, was made in October 2003. Pl. SOF Opp. SJ Pun. at ¶ 36.

Based on the foregoing, Defendant maintains it did not know about ONJ risks and, therefore, could not have deliberately concealed or failed to disclose such knowledge. NPC seeks dismissal of Plaintiffs' failure-to-warn claim as a matter of law because Plaintiffs cannot rebut the presumption that NPC's warning was adequate at the time Ms. Bessemer was prescribed Aredia/Zometa®.

Here, the court finds Plaintiffs offered sufficient evidence for a jury to determine that Defendant deliberately concealed or failed to disclose information regarding ONJ prior to FDA-approval of Aredia/Zometa®. The following information was available to Defendant prior to the FDA's approval of Aredia/Zometa®: the Gotcher & Jee article; Pl. SOF Opp. SJ Pun. at ¶ 11, similarities in biological mechanisms between bisphosphonates and certain diseases; see id. at ¶¶ 9-10, and information about phossy jaw, see id. at ¶¶ 16-19. The Gotcher & Jee article, and the fact that NPC's head of preclinical studies had this article in his files as early as 1986, raises an issue of fact as to NPC's knowledge of the poteutial risk of ONJ associated with bisphosphonate use prior to the FDA's approval of Aredia® in 1991. A finder of fact can consider the failure of NPC to provide a copy of the Gotcher & Jee article to the FDA when Aredia® was under initial

knew, or deliberately concealed, information regarding the risk of ONJ associated with bisphosphonates. Therefore, Plaintiffs have offered sufficient evidence to rebut the presumption of adequacy under the PLA. As such, summary judgment is not appropriate as to Plaintiffs' failure-to-warn claim.

b. The McDarby Exception

Subsequent to Perez, the Appellate Division recognized a separate exception to the PLA's presumption of adequacy. In McDarby, the Appellate Division held that the presumption of adequacy may also be overcome where a plaintiff shows "substantial evidence" that a pharmaceutical company engaged in "economically-driven manipulation of the post-market regulatory process." McDarby, supra, 401 N.J. Super. at 81.

Defendant alleges Plaintiffs cannot offer the type of evidence required by McDarby to rebut the presumption that NPC's warning was adequate; i.e., Plaintiffs have not shown that NPC manipulated the post-market regulatory process in any fashion that would have affected the timing or adequacy of the warning changes. See McDarby, supra, 401 N.J. Super. at 69. According to NPC, there is no expert testimony suggesting any such wrongdoing with regard to the post-marketing regulatory process. None of Plaintiffs' experts opine that NPC should have warned of the alleged risk of ONJ prior to the September 2003 labeling change. Indeed, Defendant cites testimony from Plaintiffs' expert, Dr. Marx, stating that the alleged risk of ONJ resulting from bisphosphonate therapy was "unknown [before] August 2003." Def. SUF at ¶ 85. NPC notes it voluntarily changed the drug's label the same month that Dr. Marx published the first case reports describing ONJ in Aredia/Zometa® patients. Def. SUF at ¶ 114. Defendant maintains it could not have provided warnings about the potential risk of ONJ at the time Ms. Bessemer was prescribed Aredia® or Zometa® because it did not know about those risks at that

time. See In re Diet Drug, 384 N.J. Super. at 534. According to NPC, beeause it had no awareness of any potential risk of ONJ at the time, it could not have manipulated the post-market regulatory proeess. In view of these assertions, Defeudant, as a matter of law, seeks summary judgment on Plaintiffs' failure-to-warn elaim.

In McDarhy, the eourt found that the facts of that case warranted "reeognition of an additional basis for overcoming the presumption of adequacy set forth in the PLA, applieable to [defendant] in the post-market warning context." McDarby, supra, 401 N.J. Super. at 63. The eourt explained that "[f]acts unavailable to the Supremc Court at the time of the Perez decision demonstrate that [proof of deliberate concealment or nondisclosure] is too narrow," and so the court was "unwilling to aecept [defendant's] position that the presumption of adequacy of a prescription drug's label can be overcome only upon proof of deliberate concealment or nondisclosure." Id. at 66. Instead, the court found "substantial evidence" of the drug manufacturer's manipulation of the post-market regulatory process was also suffieient to overcome the PLA's rebuttable presumption that an FDA-approved warning is adequate. Id. at 71.

In determining there was "substantial evidence" of manipulation of the post-market regulatory proeess, the McDarby court found that the drug company's failure to run tests specific to cardiovascular ("CV") risks[10] ". . . likely contributed to the absence of specific knowledge of causative factors." Id. at 67 n.36. The McDarby court also found the drug eompany engaged in post-market manipulation, in part, by attempting to explain the adversc CV effeets as consistent

[10] Although the New Drug Application ("NDA") was approved despite the FDA's knowledge of these study results, the FDA's medical review officer recommended further CV testing by the manufacturer. McDarby, supra, 401 N.J. at 67. Such tests were not conducted by the manufacturer. Ibid.

with other "known" cases of CV diseases, despite the fact that the allegedly-"known" cases had not been scientifically validated. Id. at 67-68.

Further, according to the court in McDarby, throughout the time the manufacturer was working with the FDA on a new label, the drug company "engaged in strenuous efforts to ensure that the results of the [adverse] study were not communicated to prescribing physicians by sales persons . . . ." Ibid. In determining the inadequacy of the drug's label, the McDarby court found it relevant that the label was revised subsequently to reflect adverse study results known to the drug company at least two years before the new label was issued. Id. at 69.

In this case, while NPC submitted the first adverse reports to the FDA in a timely manner, see Def. SUF at ¶¶ 87, 89-95, the court finds Plaintiffs have offered "substantial evidence" that Defendant engaged in "economically-driven manipulation of the post-market regulatory process," McDarby, supra, 401 N.J Super. at 63. According to Plaintiffs, the lack of specific ONJ studies by Defendant likely contributed to the absence of specific knowledge of causative factors similar to the McDarby case. See McDarby, supra, 401 N.J. Super. at 67 n.36. Plaintiffs also allege Defendant placed false information in the September 2003 label to downplay the risk of ONJ associated with Aredia/Zometa®. Pl. SOF Opp. SJ Pun. at ¶¶ 31-35. According to Plaintiffs, NPC claimed there were other "well-documented risk factors" for ONJ without having support for that assertion. See id. at ¶¶ 47-80. Plaintiffs allege that NPC employed 21 C.F.R. § 314.70(c) so it could minimize the risk of ONJ and update the drug's label unilaterally, without the FDA's prior approval.

Moreover, Plaintiffs proffer evidence suggesting NPC sought to avoid publication of adverse articles regarding Aredia/Zometa®. See Pl. SOF Opp. SJ Pun. at ¶ 23. This evidence is similar to the evidence presented in McDarby where in the manufacturer allegedly sought to

avoid dissemination of adverse study results. See McDarby, supra, 401 N.J. Super. at 68. Plaintiffs also present evidence showing a change to the Zometa® label in September 2007, removing the words "well documented" from the ONJ section of the label, Pl. SOF Opp. SJ Pun. at ¶¶ 59-60, because Defendant's epidemiologist assigned to work on the ONJ issue knew prior to the label change that there was "very little well-documented knowledge regarding ONJ," id. at ¶¶ 56-57.

Lastly, Plaintiffs note the September 2003 warning of ONJ risks appeared in the "Adverse Reactions" section, rather than the "Warnings" section of the Zometa® label. See McDarby, supra, 401 N.J. Super. at 69 (finding that a drug's revised warning appearing in the "Precaution" section of the label, rather than the "Warnings" section, provided powerful evidence of the drug company's manipulation of the post-marketing regulatory process). In light of these asserted facts, the court finds Plaintiffs have presented "substantial evidence" of manipulation of the post-market regulatory process sufficient to overcome the PLA's presumption of adequacy of an FDA-approved drug warning. See McDarby, supra, 401 N.J. Super. at 71.

4. The Learned Intermediary Doctrine

Defendant also relies on the learned intermediary doctrine in support of its summary judgment motion. According to Defendant, NPC's duty to warn ran only to Dr. Sharon, the oncologist who prescribed Aredia® and Zometa® to Ms. Bessemer. Thus, by providing an FDA-approved warning to Dr. Sharon, NPC maintains it discharged its duty to warn.

The PLA provides:

> An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe

> use of the produet, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used . . . .
>
> [N.J.S.A. § 2A:58C-4.]

New Jersey, like other jurisdictions, "accept[s] the proposition that a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." Niemiera by Niemiera v. Schneider, 114 N.J. 550, 559 (1989) (citing Bacardi v. Holzman, 182 N.J. Super. 422 (App. Div. 1981)). If the warning adequately "tak[es] into account the characteristics of, and the ordinary knowledge common to, the prescribing physician," then a drug manufacturer will not be liable under the PLA. Niemiera, supra, 114 N.J. at 559.

To the extent any warning would have prevented the harm allegedly suffered by Ms. Bessemer, Defendant contends the September 2003 and March 2004 labels informed oncologists, such as Dr. Sharon, about the risk of ONJ associated with Aredia/Zometa®. Accordingly, Defendant maintains, it provided a timely and adequate warning of the potential risk of ONJ to Ms. Bessemer's oncologist as soon as Defendant knew of the risk. Thus, the court must address whether Plaintiffs offer sufficient evidence to show that Defendant's warning to Ms. Bessemer's prescribing physician was less than adequate.

Here, Plaintiffs submit evidence sufficient for a jury to find that Defendant failed to communicate adequate information as to the risk of ONJ associated with Aredia/Zometa®. See N.J.S.A. § 2A:58C-4. In addition to the evidence set forth earlier in the court's memorandum, Plaintiffs claim the language suggesting "other well documented multiple risk factors" of ONJ was placed in the September 2003 and the March 2004 labels to downplay the actual risk of ONJ

associated with Aredia/Zometa® and, in fact, did downplay the risk such that the language failed to adequately warn prescribing physicians. See Pl. SOF Opp. SJ Pun. at ¶¶ 56-60.

Plaintiffs also submit evidence that an NPC epidemiologist assigned to work on the ONJ issue during the relevant time period stated there is "very little well-documented knowledge regarding ONJ." Id. at ¶¶ 56-57. Thus, Plaintiffs argue the "well documented" language was included expressly to minimize the risk of ONJ associated with Aredia/Zometa.[11] Further, Plaintiffs note the Zometa® label was eventually changed in September 2007 to remove the words "well documented" from the label, stating, as of 2007, such factors (now reduced from eight factors to two factors) "*may* be a risk factor for ONJ." Id. at ¶¶ 59-60 (emphasis added).

The court finds Plaintiffs offered evidence sufficient for a jury to determine that the pre-September 2003 label, the September 2003 label, and the March 2004 label downplayed the risk of ONJ thereby failing to adequately warn prescribing physicians of the risk of ONJ associated with Aredia/Zometa®. As such, summary judgment premised upon the learned intermediary doctrine is denied.

5. Direct-to-Consumer Advertising

Plaintiffs claim NPC is not entitled to the benefit of the learned intermediary doctrine because Defendant allegedly marketed directly to Ms. Bessemer through magazine advertisements. See Perez, supra, 161 N.J. at 19. While a pharmaceutical manufacturer generally has no duty to warn the consumer directly, the learned intermediary doctrine does not apply to "the direct marketing of drugs to consumers" where the consumer alleged he was influenced by the advertising campaign for the drug. Perez, supra, 161 N.J. at 14-15.

[11] This statement by NPC's epidemiologist was expressed in 2005, after Plaintiff ceased taking Aredia/Zometa®. However, it is for the jury to determine whether there were ever any "well-documented multiple risk factors" at any time.

In support of this argument, Plaintiffs submit a certification from Ms. Bessemer attaching a copy of a Zometa® advertisement, alleged to have appeared in CURE Magazine from Winter 2003 to Winter 2004, along with Zometa/Aredia®-related artieles appearing in CURE Magazine from Spring 2002 through Spring 2004. Revised Certification of Jane Bessemer in Opposition to Summary Judgment ("Bessemer Rev. Cert."), Exhibits 1-6.

During her deposition, Ms. Bessemer denied seeing any Aredia/Zometa® advertisements before or while she was on Aredia/Zometa®. Deposition of Jane Bessemer ("Bessemer Dep.") at 191:22-192:10. In her April 2010 certification, Ms. Bessemer described being recently shown a Zometa® advertisement in an old issue of CURE Magazine. Bessemer Cert. ¶ 3.[12] Ms. Bessemer now claims that, when she originally saw the CURE Magazine articles for Zometa®, she thought: "I'm on the right traek." Bessemer Cert. ¶ 4.[13] According to her revised certification, Ms. Bessemer "believe[d]" the Zometa® website, from the time period 2002 to 2004, did not mention ONJ.[14] Bessemer Cert. ¶ 12. Based on (a) the Zometa® advertisement and the Aredia/Zometa® articles, (b) Ms. Bessemer's purported reliance on the advertisement and articles in deciding to continue treatment with Zometa®, and (c) Ms. Bessemer's "belief" that the Zometa® website failed to warn of the risk of ONJ, Plaintiffs elaim the learned intermediary doctrine is inapplicable in this case and, thus, Defendant had a duty to warn Ms. Bessemer directly of the alleged risk of ONJ associated with Aredia/Zometa®.

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[12] The Zometa® advertisement is a one-page advertisement with nine words of copy, a logo, and a website address. Bessemer Rev. Cert., Exhibit 4, 5. On a plain dark baekground, with lighter text, the advertisement states: "Ask your doctor if ZOMETA is right for you." Ibid. Toward the bottom of the page is the product logo: "ZOMETA / (zoledronic acid) Injection," and just below that: "For more information, visit our Web site at www.ns.ZOMETA.com." Ibid.

[13] In their opposition brief, Plaintiffs claim "Mrs. Bessemer had the Aredia® advertisement in her possession, produced it to Novartis, and was questioned about it at her deposition." Pl. Opp. Brief. at 18. However, Plaiutiffs offer no citatiou to the record to support this contention. See Pl. Opp. Brief.

[14] Nowhere in her certification does Ms. Bessemer explicitly state she aetually visited the Zometa® website at this or any other time relevant to this case.

As discussed in this memorandum, Plaintiffs proffered sufficient evidence for a jury to conclude NPC failed to warn anyone in the medical community of the risk of ONJ, let alone consumers. Because the court has determined that Plaintiffs survive summary judgment premised upon NPC alleged failure to warn the prescribing physician, the court need not address the direct-to-consumer exception in the context of a failure-to-warn claim.

6. Duty to Warn Non-Prescribing Treating Physicians

Plaintiffs also argue the learned intermediary doctrine is inapplicable because Defendant had a duty to warn the dental community, not just the prescribing physician. Basing their argument on the Restatement (Third) of Torts: Products Liability § 6 and an unpublished opinion, White v. Novartis Pharmaceuticals Corp., 2009 WL 2497692, *4 (M.D. Tenn. Aug. 13, 2009), Plaintiffs contend Defendant had a duty to warn all dentists and oral maxillofacial surgeons of the alleged risk to patients undergoing dental procedures while on bisphosphonates because dentists and oral surgeons were in a position to reduce the risk of harm. In support of their contention, Plaintiffs cite the Rest. (3d) of Torts: Prod. Liab. § 6:

> . . . [a] prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to . . . prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings . . . .
>
> [Rest. (3d) of Torts: Prod. Liab. § 6.]

Plaintiffs assert Section 6 is "black-letter law" in New Jersey. Pl. Opp. Br. at 25. Plaintiffs further declare New Jersey law follows the Rest. (3d) of Torts in products liability cases, citing New Jersey products liability opinions that have relied on other sections of the Rest. (3rd) of Torts. Plaintiffs urge this court to find Section 6 of the Restatement applicable to this case.

The court declines to adopt Plaintiffs' position. Such a ruling would require the court to adopt a section of the Rest. (3d) of Torts that has not been adopted or incorporated by any New Jersey court. Neither of the cases relied upon by Plaintiffs discuss, or even mention, Section 6 of the Restatement.[15]

Further, the out-of-state cases cited by Plaintiffs do not embrace the expansive nature of Section 6 of the Restatement. Plaintiffs rely on the following language from an opinion issued in the White case: "Under the circumstances of this case, it is sufficient for Plaintiff to survive summary judgment to show that one of Mr. White's treating physicians, not simply the prescriber, would have behaved differently. Given additional knowledge, Plaintiff's oncologist might have still prescribed the drug, but Plaintiff himself and/or Plaintiff's dentist or oral surgeon might have behaved differently." White, supra, 2009 WL 2497692 at *4. Although the White case involved a claim against NPC for failure to warn of the risk of ONJ associated with Aredia/Zometa®, the White case applied California law and did not interpret the New Jersey PLA. Even assuming, *arguendo*, that the White court explicitly adopted Section 6 of the Rest. (3d) of Torts, it remains that no court in New Jersey has done so.

Furthermore, the quoted text from the White case addressed proximate cause under California law, not whether there was an additional duty to warn the dental community. See White, supra, 2009 WL 2497692 at *4. While the actions of a treating dentist or oral surgeon may be relevant to the issue of proximate cause, a jury's consideration of the acts of a treating dentist or oral surgeon does not translate into an additional duty to warn non-prescribing physicians. The issues of duty to warn and proximate cause are separate inquiries for a jury to resolve.

[15] Jerista v. Murray, 185 N.J. 175, 198, n.3 (2005) and Dean v. Barrett Homes, Inc., 406 N.J. Super. 453, 465 (App. Div. 2009).

Moreover, the language of Section 6 of the Rest. (3d) of Torts conflicts with the PLA and New Jersey case law. The PLA does not impose an additional duty on manufacturers to warn "other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings." See Rest. (3d) of Torts: Prod. Liab. § 6. The exceedingly broad category articulated by the Restatement extends well beyond the limited class of persons who must be warned as established through the PLA and relevant New Jersey case law. Thus, a duty to warn "other health-care providers" is contrary New Jersey products liability law.

Because members of the dental community, specifically Ms. Bessemer's non-prescribing physicians (e.g., her dentists and oral surgeons), do not fall into the class of persons to whom there is a duty to warn under the PLA – i.e., consumers, see N.J.S.A. § 2A:58C-4, or learned intermediaries, see ibid.; Perez, supra, 161 N.J. at 9 n.3 (citing Perez, supra, 313 N.J. Super. at 515-16) – the court finds Defendant had no duty to warn Ms. Bessemer's non-prescribing physicians. The court rejects Plaintiffs' notion that NPC had a duty to warn the dental community at large, or even Ms. Bessemer's individual non-prescribing treating physicians, of the alleged risk of ONJ related to Aredia/Zometa®.

7. Proximate Causation

It is well established that "[c]ausation is a fundamental requisite for establishing any product-liability action." James v. Bessemer Processing Co., 155 N.J. 279, 297 (1998) (quoting Coffman v. Keene Corp., 133 N.J. 581, 594 (1993)). In addition to showing there was a failure to warn, a plaintiff in a pharmaceutical produets liability action must also "demonstrate so-called product-defect eausation – that the defect in the product was a proximate cause of the injury. When the alleged defeet is the failure to provide warnings, a plaintiff is required to prove that the

absence of a warning was a proximate cause of his harm." Ibid. (quoting Coffman, supra, 133 N.J. at 594).

Defendant argues summary judgment should be granted on Plaintiffs' failure-to-warn claim because Plaintiffs failed to offer evidence that NPC's alleged failure to warn was the proximate cause of Ms. Bessemer's injury. While Plaintiffs must show an adequate warning of the risk of ONJ would have prevented Ms. Bessemer from being harmed by her use of the drug,[16] because New Jersey courts have adopted a "heeding presumption," Plaintiffs do not have the initial burden to produce such evidence.

a. The Heeding Presumption

In New Jersey, "[a] plaintiff suing under a failure-to-warn theory must presumably establish that [he or] she would have heeded an adequate warning if one were given." Perez, supra, 161 N.J. at 28 (quoting Lloyd C. Chatfield II, Medical Implant Litigation and Failure to Warn: A New Extension for the Learned Intermediary Rule, 82 Ky. L.J. 575, 582-83 (1993-94)). However, "[d]ue to the individualized nature of the inquiry into what warning would have caused the plaintiff to alter [his or] her behavior, . . . predicting how additional information would have affected any given individual may be well nigh impossible." Ibid. (quoting Chatfield, A New Extension for the Learned Intermediary Rule, 82 Ky. L.J. at 582-83). Based upon this very dilemma, New Jersey adopted the heeding presumption.[17] See Coffman v. Keene Corp., 133 N.J. 581, 597-98 (1993).

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[16] As addressed in the "Medical Causation" section of this memorandum, Plaintiffs must also establish the drug actually caused Ms. Bessemer harm.

[17] The heeding presumption grew out of public policy concerns. "The public policy goals articulated included: focusing on the underlying purpose of product liability law which concentrates on a product rather than a defendant's negligence; encouraging 'manufacturers to produce safer products, and to alert users of the hazards arising from the use of those products through effective warnings; simplifying the trial process and plaintiff's burden

The heeding presumption "provides the plaintiff with a rebuttable presumption on the issue of proximate cause [that], if a[n] [adequate] warning or instruction had been given, such warning or instruction would have been heeded by the plaintiff." Sharpe v. Bestop, Inc., 314 N.J. Super. 54, 68 (App. Div. 1998), aff'd o.b., 158 N.J. 329 (1999); see also In re Diet Drug, supra, 384 N.J. Super. at 544.[18] In cases where the heeding presumption is applicable:

> . . . the burden of production on the issue of proximate cause shifts to the defendant to come forward with rebuttal evidence.[19] In essence, the defendant's burden of production requires evidence sufficient to demonstrate . . . that a warning would have made known to the plaintiff the danger of the product and, notwithstanding the knowledge imparted by the warning, the plaintiff would have proceeded voluntarily and unreasonably to subject him or herself to the dangerous product. . . . If the defendant fails to meet its burden of production to the trial court's satisfaction, the trial judge is required to direct a verdict in favor of the plaintiff on the issue of proximate causation. If, however, the defendant presents rebuttal evidence such that reasonable minds could differ as to whether the warning, if given, would have been heeded by the plaintiff, the defendant has satisfied its burden of production and the plaintiff loses the benefit of the presumption. The plaintiff must then carry the burden of persuasion as to proximate cause.
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> [Sharpe, supra, 314 N.J. Super. at 68-69 (internal citations and quotations omitted); see also In re Diet Drug, supra, 384 N.J. Super. at 544.]

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of proof; and, minimizing the likelihood that causation decisions will be based on unreliable evidence." In re Diet Drug, supra, 384 N.J. Super. at 532 (quoting Coffman, supra, 133 N.J. at 599).

[18] The heeding presumption applies to all warning cases, see, Sharpe, supra, 314 N.J.Super. at 68, including prescription drug cases, see In re Diet Drug Litigation, 384 N.J. Super. 525 (Law Div. 2005). See also McDarby, supra, 401 N.J. Super. at 80.

[19] Under N.J.R.E. 301, once the party against which the presumption has been applied produces sufficient evidence to rebut it, the presumption disappears. The Rule reads:

> . . . a presumption discharges the burden of producing evidence as to a fact (the presumed fact) when another fact (the basic fact) has been established. If evidence is introduced tending to disprove the presumed fact, the issue shall be submitted to the trier of fact for determination unless the evidence is such that reasonable persons would not differ as to the existence or nonexistence of the presumed fact. If no evidence tending to disprove the presumed fact is presented, the presumed fact shall be deemed established if the basis fact is found or otherwise established. The burden of persuasion as to the proof or disproof of the presumed fact does not shift to the party against whom the presumption is directed unless otherwise required by law.
>
> [N.J.R.E. 301.]

Even if the prescribing physician did not actually know of the risk at the time he or she prescribed the drug, summary judgment in favor of the drug manufacturer may be appropriate where a prescribing physician testifies that, if provided with an adequate warning, he or she would have: (a) "prescribed [the drug] anyway" and (b) "would not have communicated the risk information to the plaintiff." In re Diet Drug, supra, 384 N.J. Super. at 545 (citing Strumph, supra, 256 N.J. Super. 309). However, where the prescribing physician indicates he or she would have informed the plaintiff of the risk, thus negating the second requirement, there remains an issue of fact as to proximate causation. Ibid. The In re Diet Drug court explained:

> [i]n modern medicine, the decision-making process as to whether or not to employ a particular recommended treatment, including the use of prescription drugs, is collaborative. The physician should explain to the patient the risks and benefits of the medical procedure, as well as any reasonable alternatives. Ultimately, the patient, armed with this information, makes the decision whether to proceed.
>
> [In re Diet Drug, supra, 384 N.J. Super. at 539.]

Thus, "[i]f the plaintiff denies that he or she would have taken the drug based on those warnings, then the matter will be presented to a jury with the plaintiff bearing the burden of proof on this causation issue." Ibid. (citing Sharpe, supra, 314 N.J. Super. at 63).

NPC cites the testimony of Plaintiff's prescribing physician, Dr. Sharon, stating a more adequate warning would not have stopped him from treating Plaintiff with Aredia/Zometa®. Defendant claims Dr. Sharon acknowledged he may have been aware of some reports of the association between Zometa® and ONJ in April/May 2004, and that these reports did not affect his treatment of Plaintiff's condition. Def. SUF at ¶ 29. When asked whether he knew of "any reports in the literature of [ONJ] occurring in patients taking bisphosphonate[s]" prior to May 2004, Dr. Sharon responded he "[didn't] specifically remember, but there may have been some, you know, odd, you know, report that [he] may have seen ," and he "[couldn't say] for sure that

[he] didn't" see any; he simply "[didn't] remember any." Deposition of David J. Sharon, M.D. ("Sharon Dep.") at 134:19-135:11. Dr. Sharon's testimony fails to establish that he prescribed Aredia/Zometa® to Plaintiff despite being fully aware of the risk. Thus, the court finds there is an issue of material fact as to proximate cause in this case.

Defendant also asserts there is no issue of fact as to proximate cause beeause Dr. Sharon, knowing what he knows today, would still have prescribed Aredia/Zometa® to Ms. Bessemer,[20] Def. SUF at ¶ 124, and so, even if NPC had warned of ONJ prior to its first label change in September 2003, it would not have changed Dr. Sharon's decision to prescribe the drug to her. See In re Diet Drug, supra, 384 N.J. Super. at 545 (a defendant may rebut the heeding presumption if there is evidence that an informed preseribing physician would have prescribed the drug anyway and would not have communicated the risk at issue to the plaintiff). Dr. Sharon's testimony does not support a finding, as a matter of law, that an adequate warning would not have been passed on to Plaintiff. Defendant concedes Dr. Sharon warns his patients about the risk of ONJ associated with bisphosphonate treatment. In his deposition, Dr. Sharon stated he would "discuss[] with patients the potential risks and benefits of those [Aredia/Zometa®] as [he] understood them at the time." Sharon Dep. at 70:9-20. Dr. Sharon also explained he "[does not] start anybody on a medication without explaining to them what the benefits of that medication are and what my understanding of the risks . . . at that time," ibid., and informs his patients of "the potential risk of [ONJ] from taking the drug Zometa," Sharon Dep. at 75:8-13.

[20] Defendant also offers evidenee that Dr. Sharon would still prescribe Aredia/Zometa® to Plaintiff in his current practice, Def. SUF at ¶ 125, still prescribes Zometa® to treat patients with bone metastases (like Ms. Bessemer) despite his awareness of the risk of ONJ, id. at ¶¶ 126-127, and considers such treatment the standard of care in his field, ibid. In addition, as to those patients still treating with Zometa®, Dr. Sharon believes the benefits of Zometa® outweigh the associated risk of ONJ. Id. at ¶ 128.

Based upon the testimony of Dr. Sharon, Defendant cannot satisfy the second requirement of the In Re Diet Drug analysis – that the prescribing physician would not have passed the warning on to the patient. According to Dr. Sharon, he has always discussed the risks associated with Aredia/Zometa® with his patients. This testimony, coupled with evidence that Dr. Sharon now discusses the alleged risk of ONJ associated with Zometa®, could allow a jury to conclude that Dr. Sharon would have communicated such risk to Ms. Bessemer if he had been adequately warned. As such, there remains a question of fact as to whether Ms. Bessemer would have taken, or continued to take, Zometa® upon being informed of the alleged association between the drug and ONJ.

Plaintiffs assert issues of material fact regarding whether Ms. Bessemer would have heeded an adequate warning to preclude summary judgment in favor of Defendant. When she was asked during her deposition whether, "[i]f Dr. Sharon had told [her] there was a 5 percent chance [she] would develop ONJ but he thought the drug was still effective at protecting your bone, [she] would . . . still have taken Aredia® or Zometa®," Ms. Bessemer responded that she would not. Bessemer Dep. at 209:7-13. Ms. Bessemer explained, "[i]f [she] had known what [she] know[s] now, [she] would certainly not have taken it." Id. at 209:17-21. Ms. Bessemer also testified she does not know whether, at the time, she would have taken Aredia/Zometa® if confronted with a 5% risk for developing ONJ. Def. SUF at ¶ 130; Bessemer Dep. at 210:5-17. Ms. Bessemer's testimony raises a question of fact for the jury to resolve as to whether she would have heeded an adequate warning if one had been provided.

In further support of its heeding argument, Defendant cites Ms. Bessemer's deposition testimony that she has never declined to follow Dr. Sharon's treatment recommendations. Def. SUF at ¶ 130; Bessemer Dep. at 210:13-17. This testimony, viewed in conjunction with

Plaintiff's statement that she may not have taken Aredia/Zometa® had she known of an increased risk of ONJ, raises a question of material fact for the jury to resolve as to whether Plaintiff would have heeded a warning if had one been communicated to her by Dr. Sharon.

b. Issues of Proximate Cause Unrelated to the Heeding Presumption

Defendant asserts Plaintiffs cannot show that a pre-bisphosphonate dental evaluation, as suggested in the post-Mareh 2004 label, would have prevented the development of Ms. Bessemer's ONJ. In support of this argument, Defendant asserts Plaintiffs failed to offer any evidence to support the notion that a patient is at reduced risk for developing ONJ if the patient undergoes a dental examination. Defendant relies on the testimony of Dr. Marx, Plaintiffs' expert, stating pretreatment dental screenings have not been shown to reduce the incidence of ONJ.[21]

Defendant further contends there is no evidence Ms. Bessemer required any additional dental treatment when she began taking Aredia®. Defendant argues a warning suggesting a pre-bisphosphonate dental evaluation would not have resulted in a different course of action with regard to Plaintiff's dental care; i.e., Plaintiff would have undergone the same dental procedure that was allegedly instrumental in her development of ONJ – the extraction of tooth #31 in June 2000.[22] Therefore, Defendant concludes Plaintiffs cannot prove NPC's failure to recommend a pretreatment dental evaluation was a proximate cause of her injury.

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[21] During his deposition, Dr. Marx testified "the jury is still out in terms of controlled data" on whether pretreatment dental screenings are, effective in reducing the incidence of ONJ. Deposition of Robert Marx DDS., May 26, 2009 ("5/26/09 Marx Dep.") at 1367:11-15. Dr. Marx also stated it is ". . . an unknowable situation at this point," whether a pretreatment dental screening would have prevented any individual patient from developing ONJ. 5/26/09 Marx Dep. at 1367:24-1368:4.

[22] Plaintiffs' expert, Dr. Kraut, conceded there is no evidence that Ms. Bessemer would not have developed ONJ if she had had a pretreatment dental evaluation. Def. SUF at ¶ 139.

Whether a pretreatment dental examination may reduce a patient's risk of developing ONJ is a question to be resolved by the jury. The jury may consider the "Warnings and Precautions" section of the current Zometa® label, which states "[c]ancer patients should . . . have a dental examination with preventive dentistry prior to treatment with bisphosphonates." Current Zometa® Prescribing Information Label (as of April 30, 2010), available at http://www.pharma.us.novartis.com/product/pi/pdf/Zometa.pdf. The jury may also consider Dr. Sharon's testimony that he now advises patients to have a dental evaluation before beginning treatment with Aredia/Zometa®. Def. SUF at ¶ 129: Sharon Dep. at 76:3-15.

Furthermore, Dr. Marx indentified various steps that may be taken to prevent and treat bisphosphonate-induced ONJ. Expert Report of Robert E. Marx, DDS ("Marx Report"), ¶ 18. In his report, Dr. Marx wrote:

> [p]rior to beginning bisphosphonate therapy [he and his coworkers] recommend[] that the oncologist refer patients to a dental provider for an evaluation and placement on a surveillance schedule. [They] recommend that the dentist remove unsalvageable teeth and treat any infections present prior to cleanings, restoration of decayed teeth and preventative dental counseling.
>
> [Marx Report, ¶ 52.]

Dr. Marx also cites a 2008 article reporting "carefully and regularly scheduled dental assessments . . . in all of our patients . . . exposed to [bispbosphonates] has seemed to benefit in the prevention of ONJ, showing that the collaboration between dental and oncology teams is essential to the prevention, early identification and management of ONJ." Marx Report, ¶ 54 (quoting A.M. Cafro, Osteonecrosis of the jaw in patients with multiple myeloma treated with bisphosphonates: definition and management of the risk related to zoledronic acid, 2008 ("Cafro 2008"), at p. 115 (internal quotations omitted)). Accordingly, there remains a question of fact as to whether a pretreatment dental screening can prevent the development of ONJ in a patient

receiving Aredia/Zometa®. Because there is a question of fact as to (a) whether pretreatment dental evaluations may prevent ONJ and (b) whether a warning advising a patient to undergo pretreatment dental evaluations would have materially altered the course of Plaintiff's dental care, summary judgment on the issue of proximate cause is denied.

Defendant argues Plaintiffs have failed to show proximate cause because a warning that extractions should be avoided in patients taking Aredia/Zometa® would not have had any bearing on the extraction of tooth #31, which allegedly was a catalyst in Ms. Bessemer's development of ONJ. Defendant asserts the extraction of tooth #31 was unavoidable.[23] Regardless of whether the extraction was "unavoidable," there remains an issue of material fact as to whether a pretreatment dental exam would have enabled Ms. Bessemer's doctors to remove that tooth prior to her course of treatment with Aredia/Zometa®, as recommended in the current Zometa® label. See current Zometa® Prescribing Information Label (as of April 30, 2010), available at http://www.pharma.us.novartis.com/product/pi/pdf/Zometa.pdf., Def. SUF at ¶ 129; Sharon Dep. at 76:3-15, Marx Report, ¶¶ 18, 52, and the Cafro 2008 article, see id. at ¶ 54. Plaintiffs counter Ms. Bessemer's ONJ might have been prevented, or the harm resulting therefrom mitigated, if Ms. Bessemer had the tooth extracted earlier. Thus, there remains an issue of material fact as to whether an earlier warning would have resulted in Ms. Bessemer stopping Zometa® prior to April 2004, thus preventing, or mitigating, her ONJ. Accordingly, summary judgment on the issue of proximate cause is denied.

Lastly, in support of summary judgment on the issue of proximate cause, Defendant contends Plaintiffs failed to show that Ms. Bessemer's condition would have been prevented if

[23] Defendant points to testimony from Dr. Dooley that he recommended extracting tooth #31 because it had severe caries and was non-restorable, Def. SUF at ¶ 38, and testimony from Plaintiffs' case specific expert, Dr. Kraut, that the extraction of tooth #31 was unavoidable, id. at ¶ 40.

she had taken a drug holiday from her Aredia/Zometa® treatment to undergo the tooth extraction. Defendant argues Aredia/Zometa® remains in the bones for more than 10 years after ceasing treatment. Def. SUF at ¶ 141.[24] According to Defendant, Ms. Bessemer could not have taken a drug holiday before undergoing the emergency type dental proeedure at issue bceause she was in acute, severe pain and likely had an infection in the area of tooth #31. Def. SUF at ¶ 144.

Regardless of whether a drug holiday was an option in this case and whether a drug holiday would have prevented or mitigated Ms. Bessemer's ONJ, there remains an issue of material faet as to whether a pretreatment dental exam would have enabled removal of tooth #31 prior to Ms. Bessemer beginning her course of treatment of Aredia/Zometa® so as to avoid any need for a drug holiday. The court also finds issucs of material fact as to whether an earlier, more adequate warning may have caused Plaintiff to try a drug holiday to prevent or retard the development of ONJ. Accordingly, summary judgment on the issue of proximate cause is denied.

[24] Defendant cited testimony from Dr. Kraut noting a lack of conclusive scientific evidence that taking patients off bisphosphonates before performing a tooth extraction prevents them from developing ONJ. Def. SUF at ¶ 142, 144. In further support of its argument, Defendant points out the American Associatiou of Oral & Maxillofacial Surgeons ("AAOMS"), in a position paper on dental treatment strategies for patients receiving bisphosphonates, wrote "[l]ong-term, prospective studies are required to establish the efficacy of drug holidays in reducing the risk of BRONJ for patients receiving oral bisphosphonates." See id. at ¶ 74, Exh. 26 (Salvatore Ruggiero, et al., American Association of Oral & Maxillofacial Surgeons Position Paper on Bisphosphonate-Related Osteonecrosis of the Jaws – 2009 Update).

5. Medical Causation

Defendant argues Plaintiffs' failure-to-warn claim cannot succeed because they have not proven that Aredia® or Zometa® are capable of causing ONJ and, specifically, that either or both drugs caused Ms. Bessemer's development of ONJ.

Under New Jersey law, "[t]here is no requirement in the law that a single cause be found and proven. All that is required is that the plaintiff show that a defendant's conduct or defective product was a proximate cause of the condition, i.e., a substantial factor in bringing the condition about." Grassis v. Johns-Manville Corp., 248 N.J. Super. 446, 457 (App. Div. 1991) (citing Brown v. United States Stove Co., 98 N.J. 155, 171 (1984)); see also Jones v. Owens-Corning Fiberglas Corp., 288 N.J. Super. 258, 267 (App. Div. 1996) (admitting expert's testimony that plaintiff's exposure to asbestos remained a significant factor in causing his colon cancer even where other risk factors, such as diet, genetic factors, rare diseases, and sedentary lifestyle could have also contributed). Hence, even where there are other causative factors present, summary judgment is inappropriate where a plaintiff shows through his or her specific causation expert that, "to a reasonable degree of medical probability," the plaintiff's use of, or exposure to, a particular product or substance was a significant factor in causing the plaintiff's injuries. Grassis, supra, 248 N.J. Super. at 457. It is for the jury to determine whether a risk factor is significant. Ibid.

Defendant maintains the testimony of Plaintiffs' specific causation expert, Dr. Kraut, is inadmissible. The court addressed this issue in a separate memorandum in response to Defendant's motion to exclude the testimony of Dr. Kraut. The court denied NPC's motion to exclude the testimony of Dr. Kraut and, therefore, Defendant's point is moot.

Defendant claims, even if Dr. Kraut's testimony is admissible, Plaintiffs cannot establish that Ms. Bessemer's use of Aredia/Zometa® was a substantial contributing factor to her development of ONJ. Despite Defendant's claim, Dr. Kraut does, in fact, rule in and rule out Ms. Bessemer's other known risk factors and provides de-challenge data to conclude Ms. Bessemer's use of Aredia/Zometa® was a substantial contributing factor to her development of ONJ. See Expert Report of Richard A. Kraut, DDS ("Kraut Report"), p. 4. Dr. Kraut rules out Ms. Bessemer's other risk factors as substantial contributing factors, opining her use of Aredia/Zometa® was the sole substantial contributing factor to the development of Ms. Bessemer's ONJ. See ibid.; see also Deposition of Richard A. Kraut, DDS ("Kraut Dep.") at 519:22-520:11, 520:25-522:25 (ruling in and ruling out potential causes of Ms. Bessemer's injury aside from bisphosphonates, including metastatic disease, osteoradionecrosis, osteomyelitis, localized osteitis, fungal infection, and primary malignancy of the jaw); id. at 524:15-25, 325:5-326:6, 344:5-345:4, 355:2-11 (discussing how some ONJ risk factors, such as chemotherapy, corticosteroids, and diabetes, were not separate and active causes of ONJ, but rather indicators that a person is at a higher risk for developing BONJ). Dr. Kraut reiterated this during his Rule 104 hearing. Taken as a whole, Dr. Kraut provided sufficient evidence and testimony to create an issue of material fact as to whether Aredia/Zometa® was a substantial factor in bringing about Plaintiff's ONJ. The credibility of Dr. Kraut's testimony, and how significant a factor the drug was in producing Ms. Bessemer's harm, are issues for the jury. Therefore, summary judgment on the issue of medical causation is denied. For this reason and the reasoning set forth in Section A of this memorandum, summary judgment on Plaintiffs' failure-to-warn claim is denied.

B. Punitive Damages

Defendant argues summary judgment should be granted as to Plaintiffs' punitive damages claim because such claims are preempted. See McDarby, supra, 401 N.J. Super. at 87-94.[25] Under the PLA, punitive damages are barred in a pharmaceutical products liability action where the drug has been approved by the FDA. N.J.S.A. § 2A:58C-5(c) ("[p]unitive damages shall not be awarded if a drug or device . . . was subject to premarket approval . . . and was approved or licensed . . . by the [FDA]"). However, the PLA has carved out an exception, allowing punitive damages where the drug-maker "knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question awarded . . . ." N.J.S.A. § 2A:58C-5(c).

In McDarby, the Appellate Division held the PLA's exception was preempted by the federal Food, Drug and Cosmetic Act ("FDCA"). McDarby, supra, 401 N.J. Super. at 94. The McDarby court found the PLA's punitive damage exception was impliedly preempted based upon the United States Supreme Court's decision in Buckman. McDarby, supra, 401 N.J. Super. at 93 (citing Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 347-49 & n.4 (2001)). Therefore, the McDarby court concluded punitive damages are unavailable under the PLA when a drug has been approved by the FDA. McDarby, supra, 401 N.J. Super. at 93-94.[26]

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[25] Defendant filed a separate motion for summary judgment on Plaintiffs' claim for punitive damages. The court addressed the issue of punitive damages in this memorandum for the court's convenienee. However, the court will issue separate orders for the motion to preclude punitive damages and the motion for summary judgment on Plaintiffs' substantive claims.

[26] Although McDarby was subsequently questioned by the U.S. District Court for the District of New Jersey in Sullivan v. Novartis Pharmaceuticals Corp., 602 F.Supp.2d 527 (D.N.J. 2009), McDarby remains binding precedent in New Jersey. The Sullivan case was decided on March 6, 2009. Two months later, on May 7, 2009, after the Sullivan opinion was issued, the New Jersey Supreme Court withdrew the petition for certification in McDarby as improvidently granted. 200 N.J. 267 (2009). The judgment below in McDarby, and the holding that punitive damages under the PLA were federally preempted, was left undisturbed.

Here, Plaintiffs argue they are entitled to punitive damages under the PLA because, unlike McDarby and Buckman, Plaintiffs do not rely solely on the claim that NPC knowingly withheld or misrepresented information to the FDA. For one, Plaintiffs argue NPC's failure to warn the dental community about the risk of ONJ constitutes punitive conduct that is unaffected by the FDA's approval of Aredia/Zometa® or the drugs' warnings. Plaintiffs base their claim on the argument that the Rest. (3d) of Torts imposes a duty to warn the dental community. See Rest. (3d) of Torts: Prod. Liab. § 6. Plaintiffs argue a duty to warn "other health-care providers" based upon the Restatement and New Jersey tort law, rather than the PLA, is unrelated to FDA approval and, thus, not preempted by the FDCA.

As explained in this memorandum, the court rejects Plaintiffs' position that pharmaceutical companies have an independent duty to warn non-prescribing physicians. New Jersey courts have not adopted Section 6 of the Rest. (3d) of Torts suggesting a duty to warn other health-care providers. Under New Jersey law, the only basis for awarding punitive is set forth in the PLA. As both Aredia® and Zometa® were approved by the FDA, punitive damages are presumptively barred pursuant to the PLA. See N.J.S.A. § 2A:58C-5(c). Because the PLA's exception in favor of awarding punitive has been preempted by the FDCA, consistent with the court's holding in McDarby, Plaintiffs' claim for punitive damages is barred.

Plaintiffs argue, alternatively, that if the punitive damages claim under the PLA is barred on the basis of pre-emption, this court must then apply New Jersey's general punitive damages statute. Under prineiples of statutory invalidation, Plaintiffs argue if one sentence of N.J.S.A. §2A:58C-5(c) is rendered invalid, then the remainder of the section must be struck as well. See N.J.S.A. § 1:1-10.

According to, N.J.S.A. § 1:1-10, where a statutory provision is deemed inoperative, "in whole or in part," such provision "shall, to the extent that it is not uneonstitutional, invalid or inoperative, be enforced and effectuated, and no such determination shall be deemed to invalidate or make ineffeetual the remaining titles, subtitles, chapters, articles, seetions or provisions." As the Supreme Court of New Jersey explained, "[w]hether such 'judicial surgery' should be utilized depends upon whether the Legislature would have wanted the statute to survive." Communications Workers of Am. v. Florio, 130 N.J. 439, 465 (1992) (quoting Chamber of Commerce v. State, 89 N.J. 131, 151-52 (1982)) (internal quotations omitted); see also Chamber of Commerce, supra, 89 N.J. at 162 (if any part of a statute is deemed inoperative, the statute shall be effectuated to the extent possible insofar as it does not "substantial[ly] impair[] . . . the principal objeet of the section") (citing Inganamort v. Borough of Fort Lee, 72 N.J. 412 (1977)).

Here, the remaining provision of N.J.S.A. § 2A:58C-5(c) – that punitive damages are unavailable under the PLA where a drug is approved by the FDA – may be constitutionally enforced so as to comport with the Legislature's intent. Based upon the language of N.J.S.A. § 2A:58C-5(c), it is clear the New Jersey Legislature intended to bar punitive damages in a failure-to-warn ease where the drug was pre-approved by the FDA. The court believes it would be contrary to the intent of the legislature for the court to ignore a drug's approval by the FDA and allow punitive damages where the statute expressly precludes such a claim when the drug at issue was FDA-approved.

The court finds N.J.S.A. § 2A:58C-5(c) bars punitive damages where a drug is approved by the FDA and follows the McDarby court's ruling that the exception to the PLA's bar on punitive damages is preempted by the FDCA. As both Aredia® and Zometa® were approved by

the FDA, summary judgment is GRANTED as to Defendant's motion to preelude punitive damages.[27]

C. Breach of Express Warranty Claim

Defendants eontend summary judgment is warranted on Plaintiffs' claim for breach of express warranty because no promise was made directly to Ms. Bessemer by Defendant.[28]

Express warranties in New Jersey are governed by Article 2 of the Uniform Commercial Code. N.J.S.A. § 12A:2-101 et seq. Section 2-313(1) of the Code recognizes express warranties arise from the following:

> (a) any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain ereates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> [N.J.S.A. § 12A:2-313(1).]

Plaintiffs offer limited facts relating to whether Defendant made promises directly to Ms. Bessemer forming the basis for her decision to take Aredia/Zometa®. Upon filing their opposition to Defendant's motion for summary judgment, Plaintiffs submitted a certification from Ms. Bessemer alleging Defendant advertised Aredia/Zometa® directly to her through advertisements, articles in CURE Magazine and a website operated by NPC. See Bessemer Rev. Cert., Exhibits 1-6. These allegations are relevant to the issue of express warranty. The

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[27] Plaintiffs also argue the court should allow the punitive damages question to go to the jury to conserve judicial resources in light of the anticipated review by the New Jersey Appellate Division on the issue of punitive damages in pharmaceutical cases. The court declines to do so. McDarby remains the law in New Jersey, and this court is bound by its holding with regard to punitive damages.

[28] A claim for breach of express warranty is not subsumed by the PLA. See Banner v. Hoffmann-La Roche Inc., 383 N.J. Super. 364, 891 (App. Div. 2006), certif. denied, 190 N.J. 393 (2007).

purported affirmations of fact in the advertisements, NPC website, and CURE Magazine may, in part, have been the basis for Ms. Bessemer's taking of the drug. See N.J.S.A. § 12A:2-313(1).

Plaintiffs pursued discovery on the direct-to-consumer advertising issue, which included depositions of several NPC employees involved in the marketing of Aredia/Zometa®. NPC employees denied any advertisements marketed directly to consumers. Plaintiffs eventually discovered the direct-to-consumer advertisements in February 2010 through the diligent efforts of their own counsel. As counsel did not have an opportunity to discuss the newly-discovered advertisements with Ms. Bessemer until February 16, 2010, and Defendant filed its motion for summary judgment on March 4, 2010, neither party had adequate opportunity to conduct the discovery necessary to resolve the breach of express warranty (via direct-to-consumer advertising) claim.

In light of these recently discovered facts, the court DENIES Defendant's summary judgment motion as to Plaintiffs' breach of express warranty claim. See Brill, supra, 142 N.J. at 533 (noting that summary judgment should be addressed ". . . after passage of adequate time to complete the discovery . . ."). The court will address this narrow issue upon completion of further limited discovery. Extended discovery limited to this narrow issue shall be raised by counsel, to be addressed by the court, at the next case management conference.

D. Plaintiff's Remaining Claims

In addition to the failure-to-warn claim under the PLA, punitive damages claim, and breach of express warranty claim, Plaintiffs assert the following claims against NPC:

(1) defective design under the PLA;

(2) breach of implied warranty under the PLA;

(3) violation of New Jersey Consumer Fraud Act;[29] and

(4) loss of consortium.

[Second Am. Compl. ¶¶ 32-77.]

1. Design Defect

The court grants summary judgment as to Plaintiffs' design defect claim under the PLA. Defendant argues Plaintiffs' design defect claim is based solely on her assertion that NPC failed to properly warn of the alleged risk of ONJ, not that the drug should be taken off the market or designed in any different way. The PLA states:

> [a] manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable, or safe for its intended purpose because it . . . was designed in a defective manner.
>
> [N.J.S.A. § 2A:58C-2.]

In support of its motion, Defendant argues the benefits of using Zometa® outweigh its risks, as acknowledged by Plaintiff's own expert, Dr. Marx. See Deposition of Robert Marx DDS, May 15, 2007 ("5/15/07 Marx Dep.") at 297:4-299:8 (testifying that physicians should not stop prescribing the drug out of fear of its risks).

In their opposition brief, Plaintiffs fail to respond to Defendant's arguments on this issue. Nor have Plaintiffs presented any expert testimony related to a design defect claim. Rather than

[29] Plaintiffs dismissed their Consumer Fraud Act claim.

identifying any genuine issue of material faet on the design defect claim, Plaintiffs argue Defendant has the burden of proving its defense to this claim. However, Plaintiffs have the burden at trial to prove each element of their claim by a preponderance of the evidenee before any burden shifts to Defendant. See N.J.S.A. § 2A:58C-2. Here, Plaintiffs offer no evidence that Aredia/Zometa® was dcfectively designed. Aeeordingly, the court GRANTS summary judgment as to Plaintiffs' design defect claim.

2. Breach of Implied Warranty

The court shall grant summary judgment as to Plaintiffs' claim for breach of implied warranty. The PLA serves as an exclusive remedy for liability arising out of product use in New Jersey. Koruba v. Am. Honda Motor Co., 396 N.J. Super. 517, 531 (App. Div. 2007). Plaintiffs' claim for breach of implied warranty must be dismissed because the PLA does not recognize it as a separate cause of action independent of an alleged defective product or alleged inadequate warning. Ibid.; see also Universal Underwriters Ins. Group v. Pub. Serv. Elec. & Gas Co., 103 F. Supp. 2d 744, 746 (D.N.J. 2000). Plaintiffs fail to rebut Defendant's argument with any specificity and fail to cite any contrary case law. Accordingly, the court GRANTS summary judgmcnt as to Plaintiffs' breach of implied warranty claim.

3. Loss of Consortium

The court denies Defendant's motion for summary judgment as to the loss of eonsortium claim filed on behalf of Plaintiff Allen Bessemer ("Mr. Bessemer"). Defendant argues this claim should fail because it is derivative of Ms. Bessemer's personal injury elaim, which, according to Defendant, fails as a matter of law. Because Plaintiffs' failurc-to-warn claim survives summary judgment, Mr. Bessemer's claim survives, and summary judgment is DENIED as to the loss of consortium claim.

Conclusion

For the foregoing reasons, Defendant's motion for summary judgment is DENIED as to Plaintiffs' failure-to-warn and breach of express warranty claims; and Mr. Bessemer's consortium claim. Summary judgment is GRANTED as to Plaintiffs' design defect claim; breach of implied warranty claim; and punitive damages claim.

JESSICA R. MAYER, J.S.C.