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, Motion *In Limine* to Exclude Evidence and Testimony, and Motion to Exclude Testimony of Plaintiffs' Expert Dr. Suzanne Parisian on the Issue of Direct-to Consumer Advertising

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

For Defendant: Beth S. Rose, Esq., Sills Cummis & Gross P.C.
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Dated: August 20, 2010

Defendant Novartis Pharmaceutieals Corporation ("NPC" or "Defendant") moves for summary judgment as to the claims of Plaintiffs Jane and Allen Bessemer ("Plaintiffs") on failure-to-warn and breach of express warranty related to direct-to-consumer ("DTC") advertising. Defendant also moves to exclude evidence and testimony, including the testimony of Plaintiffs' expert Dr. Suzanne Parisian, related to the issue of DTC advertising. The court has considered thc written submissions regarding Defendant's motions. Both parties waived oral argnments and submitted the matters to the court for resolution based upon the filed papers. The following Memorandum of Decision sets forth the court's disposition of NPC's motions.

Statement of Material Facts and Procedural History

The court repeats and incorporates the Statement of Material Facts set forth in the court's April 30, 2010, Memorandum of Decision on Defendant's Motion for Summary Judgment on Plaintiffs' Claims and Defendant's Motion to Preclude Punitive Damages ("Summ. J. Memo."), Bessemer v. Novartis Pharmaceuticals Corp., Docket No. MID-L-1835-08 (Law Div. April 30, 2010), along with the facts set forth under the "Direct-to-Consumer Advertising" heading of that Memorandum, id. at 19-21. The court, in its April 30, 2010 Memorandum, granted summary judgment as to Plaintiffs' design defect, breach of implied warranty, and punitive damages claims. See Summ. J. Memo., Bessemer, supra, Docket No. MID-L-1835-08. The court also denied summary judgment as to Plaintiffs' failure-to-warn and breach of express warranty claims and Mr. Bessemer's consortium claim. See ibid. As part of the court's ruling on Defendant's initial summary judgment motion, the court allowed additional discovery to develop Plaintiffs' failure-to-warn claim under a theory of DTC advertising – an exception to the learned intermediary doctrine. See Summ. J. Memo., Bessemer, supra, Docket No. MID-L-1835-08, at 19-21; Case Management Order No. 14. The court also deferred ruling on Plaintiffs' breach of express warranty claim to allow additional discovery limited to Plaintiffs' DTC advertising theory. See Summ. J. Memo., Bessemer, supra, Docket No. MID-L-1835-08, at 38-39; Case Management Order No. 14.

In opposition to summary judgment, Plaintiffs submitted a Certification by Ms. Bessemer ("Bessemer Cert."). The Bessemer Cert., along with Plaintiffs' opposition brief, asserted that Ms. Bessemer had seen a Zometa® advertisement,[1] along with several articles discussing

[1] The Zometa® advertisement purportedly read by Ms. Bessemer appeared in *CURE* magazine from Winter 2003 to Winter 2004.

Aredia/Zometa®,[2] in *CURE* magazine – a quarter-annual magazine marketed to cancer patients. Plaintiffs' Memorandum in Opposition to NPC's Supplemental Motion for Summary Judgment on Express Warranty and to Retain Learned Intermediary ("Pl. Opp. to Supp. Summ. J.") at 18-19; Bessemer Cert. Plaintiffs argue that these advertisements and articles qualify as DTC advertising and, thus, negate the learned intermediary doctrine under a failure-to-warn claim. Despite failing to mention the advertisements at any time prior to her Certification, even after being asked about advertising during discovery,[3] Ms. Bessemer now claims that, when she originally saw the *CURE* magazine articles for Zometa®, she thought: "I'm on the right track." Bessemer Cert. ¶ 4. According to her revised Certification, Ms. Bessemer "believe[d]" the Zometa® website, from the time period 2002 to 2004, did not mention osteonecrosis of the jaw ("ONJ"). Bessemer Cert. ¶ 12.

After three months of additional discovery on the issue of DTC advertising as it relates to Plaintiffs' failure-to-warn and breach of express warranty claims, the court revisits the basis for these claims.[4]

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[2] The Aredia/Zometa®-related articles allegedly read by Ms. Bessemer appeared in *CURE* magazine from Spring 2002 through Spring 2004. Bessemer Cert., Exh. 1-6.

[3] During her initial deposition, Ms. Bessemer denied seeing any Aredia/Zometa® advertisements before or while she was on Aredia/Zometa®. 6/26/2009 Deposition of Jane Bessemer ("6/26/2009 Bessemer Dep.") at 191:22-192:10; see also id. at 203:2-5 (in her initial deposition, responding "No" when asked if she had ". . . ever seen any advertisements of any kind[] in a magazine, newspaper, [or on] television[] about Zometa® . . ."); Plaintiff Jane Bessemer's Response to [NPC's] First Set of Interrogatories (Sept. 2006) (Certification of Charles J. Falletta in support of NPC's Supplemental Motion for Summary Judgment ("Falletta Cert.") Exh. 29) (failing to indicate in her interrogatory responses that she had seen any advertisements during her course of treatment); 7/21/2010 Deposition of Jane Bessemer ("7/21/2010 Bessemer Dep.") at 109:24-110:3 (testifying that she had indicated in her Plaintiffs' Fact Sheet that she had not seen any advertisements during her course of treatment; Def. SUF ¶ 9 (stating that Ms. Bessemer did not provided any Zometa® advertisements in response to NPC's request for production of documents).

[4] Since discovery was extended, Plaintiffs issued subpoenas to, and scheduled depositions for, several employees and freelance writers associated with *CURE*, but did not actually depose any of the employees or authors. While receiving correspondence between NPC & *CURE*, Plaintiffs did not receive other documents from *CURE* magazine, such as the advertising contract between *CURE* and NPC. While Plaintiffs explain that the deposition of the *CURE* writers would have been "wasteful" without such documents, Plaintiffs maintain that such depositions are not necessary for the court to rule on this motion. The court believes that the three month extension of discovery for the DTC issue provided ample time for both parties to develop their legal positions and arguments. The court signed

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. Breach of Express Warranty

In their Amended Complaint, Plaintiffs allege that NPC ". . . expressly warranted to [Ms. Bessemer], by and through statements made by [NPC] or its authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended

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all of the requested Orders for Commission submitted by Plaintiffs for the purpose of obtaining discovery on this issue. See Order for Commission and Commission Authorizing the Issuance of an Out-of-State Subpoena *Ad Testificandum* and *Duces Tecum* ("Order for Commission") (May 28, 2010) (compelling deposition testimony and production of documents by the custodian of records of *Coping With Cancer* magazine; Order for Commission (May 28, 2010) (for the custodian of records of *CURE* magazine); Order for Commission (May 28, 2010) (for Amy D'Orazio, a medical writer); Order for Commission (May 28, 2010) (for Melissa Knopper, a medical writer); Order for Commission (May 28, 2010) (for Beverly Caley, a medical writer); Order for Commission (June 21, 2010) (for Susan McClure for Cure Media Group, a publisher of *CURE* magazine); Order for Commission (June 21, 2010) (for the custodian of records for Palio, a marketing, advertising, and communications company); Order for Commission (June 29, 2010) (for the custodian of records for Harrison and Star, a marketing, advertising, and communications company); Order for Commission (June 29, 2010) (for Melissa Weber, a managing editor of *CURE* magazine); Order for Commission (June 30, 2010) (for Physicians' Education Resource, a medical publishing, writing, educator, and programming corporation).

The court disagrees with Plaintiffs that the depositions of writers associated with *CURE* would have been "wasteful" without a copy of the contract. To the contrary, the court believes that the depositions of the *CURE* article authors would have proven or disproven Plaintiffs' theory on the DTC advertising issue conclusively. In addition to topics outside of the four corners of the purported contract, Plaintiffs' counsel could have explored the contents of the contract with *CURE* employees and freelance writers.

for physicians, medical patients and the general public, that Aredia® and Zometa® were safe, effective, fit and proper for their intended use." Plaintiffs' Amended Complaint ("Pl. Comp.") at ¶ 58. However, Ms. Bessemer never communicated directly with anyone from NPC, 6/26/2009 Bessemer Dep. at 96:3-13, and never read the package insert for Aredia® or Zometa®, id. at 97:8-11. Instead, Ms. Bessemer asserted in Plaintiffs' Opposition to Defendant's initial summary judgment motion that the advertisement in *CURE* ". . . and [her] reliance on it is a warranty that the drug is not going to destroy her jaw." Plaintiffs' Opposition to Defendant NPC's Motion for Summary Judgment on Plaintiffs' Claims ("Pl. Opp. to Summ. J.") at 26. She also claims that, after reading the *CURE* magazine articles, along with the Zometa® advertisements contained in *CURE*, she thought she was "on the right track." Bessemer Cert. ¶ 4.

> Under New Jersey Law, the following are express warranties:
>
> (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 creates 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.
>
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.
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> [N.J.S.A. § 12A:2-313.]

As noted by Defendant, Ms. Bessemer did not see any advertisement or read any articles on Aredia® before or while she took the drug. The only Aredia® advertisement seen by Ms. Bessemer was after she had completed her Aredia® treatment. 6/26/2009 Bessemer Dep. at 190:12-191:18; 7/21/2010 Bessemer Dep. at 15:1-15. During her depositions, Ms. Bessemer testified that her decision to receive Aredia® and to stay on Aredia® was not based on any

advertisements. 7/21/2010 Bessemer Dep. at 15:11-15. Plaintiffs have offered no additional evidence to indicate that NPC made any affirmation of fact or promise to Ms. Bessemer that served as the basis of her taking (or continuing to take) Aredia®. See N.J.S.A. § 12A:2-313(a). Further, NPC made no description of the drug, or provided any sample or model, to Ms. Bessemer that was part of the basis of her taking (or continuing to take) Aredia®. See N.J.S.A. § 12A:2-313(b)-(c).

As to her express warranty claim based on the Zometa® advertisements in *CURE*, Ms. Bessemer claims to have first seen the advertisement in the Winter 2003 issue of *CURE*[5] – almost two years after she first started taking Zometa®. Thus, this advertisement could not have been the basis of Ms. Bessemer beginning treatment with Zometa®. Ms. Bessemer believes she also saw the Zometa® advertisement in the Spring, Summer, and Winter 2004 issues of *CURE*.[6] See N.J.S.A. § 12A:2-313. According to Ms. Bessemer, she did not rely on the Zometa® advertisements as the basis for her continuing Zometa®. 7/21/2010 Bessemer Dep. at 76:4-11, 78:14-23, 79:23-80:1. In her deposition, Ms. Bessemer was asked: "[w]hat in this advertisement . . . convinced you to continue to take Zometa®? What statement in the advertisement made you continue to take Zometa®?" Id. at 78:14-17. She responded that "[n]othing in this advertisement" convinced her, but rather it was the article[s] in *CURE* magazine that caused her to continue taking Zometa®. Id. at 78:18-19. Defense counsel clarified by asking: "so it was the articles in the magazine that caused you to continue taking Zometa®, not the advertisement?" Id. at 78:20-23. Ms. Bessemer answered in the affirmative. Id. at 78:23.

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[5] Ms. Bessemer testified that she never saw Zometa® advertisements in any magazine other than *CURE*. See 7/21/2010 Bessemer Dep. at 19:21-20:04, 21:1-6, 95:5-7.

[6] Because Ms. Bessemer took her last dose of Zometa® in April 2004, the only relevant copies of *CURE* magazine containing the Zometa® advertisement were the Winter 2003 and Spring 2004 issues.

The advertisement at issue makes no "affirmation of fact or promise" nor contains any "description of the goods" – i.e., an *express* warranty – to readers of the advertisement such as Ms. Bessemer. The Zometa® advertisement seen by Ms. Bessemer is a one-page advertisement containing only the product name, along with the generic drug name, a logo, a website address, and nine words of copy stating: "Ask your doctor if ZOMETA® is right for you." Bessemer Cert., Exhs. 4, 5. This advertisement makes no express assertion of fact or promise and contains no description of the drug. Ibid.

According to Plaintiffs, by placing an image of a bone in the Zometa® advertisement, NPC represented to Ms. Bessemer and other consumers that "Zometa® is good for bones." Pl. Opp. to Supp. Summ. J. at 27. However, Ms. Bessemer never testified that the Zometa® logo had any meaning to her, let alone that it conveyed any warranty about her bones. Even if Ms. Bessemer testified that the bone graphic had some impact on her, the graphic did not convey anything to her that she did not already know. Ms. Bessemer testified that she had been told when she switched from Aredia® to Zometa® (almost two years before the Zometa® advertisement in the Winter 2003 issue of *CURE*) that Zometa® was "a calcium wash to protect [her] bones." 7/21/2010 Bessemer Dep. at 45:21-23.

Regardless of whether the bone graphic in the Zometa® advertisement was intended to convey that the drug was good for a patient's bones, such communication did not amount to an *express* affirmation of fact or promise or description of the goods. See N.J.S.A. § 12A:2-313. At best, the purported warranty that "Zometa is good for bones" was implied. A drawing of a bone is not an affirmation of fact, a promise, or a description of a drug that could serve as the basis for a patient to take, or continue taking, Zometa®. As noted in the court's initial April 30, 2010 Summary Judgment Memorandum, implied warranty claims are subsumed by the PLA.

See Koruba v. Am. Honda Motor Co., 396 N.J. Super. 517, 531 (App. Div. 2007); see also Universal Underwriters Ins. Group v. Pub. Serv. Elec. & Gas Co., 103 F. Supp. 2d 744, 746 (D.N.J. 2000).

Further, the fact that the advertisement directs the consumer to the Zometa® website does not give rise to a breach of express warranty claim. Despite testifying in June 2009 that she never researched Zometa® on the internet, 6/26/2009 Bessemer Dep. at 52:5-7, and not being able to specifically recall the websites she viewed when researching breast cancer, id. at 50:8-23, Ms. Bessemer now claims to have visited the Zometa® website. 7/21/2010 Bessemer Dep. at 98:21-24, 100:21-23. However, Ms. Bessemer cannot recall when she viewed the website, id. at 99:1-3, 100:25-101:5, what she saw on the website, id. at 101:16-18, 101:25-102:2, 102:7-12, 19-22, or for how long she looked at the website, id. at 101:19-21. Despite her inability to recall anything specific about her viewing of the Zometa® website, Ms. Bessemer "believes" that the website contained no warning about ONJ. Bessemer Cert. at ¶ 12.

In analyzing a summary judgment motion, the court is required to view the evidential materials in the light most favorable to the non-moving party. However, Plaintiffs still bear the burden of proof at trial and, thus, must produce *some* evidence to create a genuine issue of material fact. See Brill, supra, 142 N.J. 520. Here, without being able to recall precisely when she viewed the Zometa® website and, more importantly, what assertions were made on the website, Ms. Bessemer's unsupported belief that the website failed to contain a warning about ONJ amounts to a "mere scintilla of evidence" that fails to meet her required burden on the issue. Id. at 529 (quoting Judson, supra, 17 N.J. at 75 (internal quotations omitted). The court cannot consider Ms. Bessemer's "belief" that the website did not contain any warning about ONJ when

Ms. Bessemer cannot affirm, or certify under oath, what information *was* on the Zometa® website at any time.

Plaintiffs also contend that the articles written in *CURE* magazine, allegedly read by Ms. Bessemer while on Zometa®, give rise to a breach of warranty claim.[7] However, none of the articles were reviewed, written, edited, or commissioned by NPC. Defendant [NPC's] Statement of Undisputed Material Facts in Support of Motion for Summary Judgment ("Def. SUF") at ¶¶ 89-100; cf., Plaintiffs' Response to Def. SUF ("Pl. Resp. SUF") at ¶¶ 86-100 (conceding that no *CURE* employees or authors were employees of NPC, but alleging that NPC had control of *CURE* authors, as discussed below).[8] Therefore, regardless of whether the articles make any affirmations of fact or promise, or other descriptions of the drug, the statements in the articles were not "made by the seller to the buyer," as required by N.J.S.A. § 12A:2-313. Plaintiffs have not submitted any evidence to indicate that *CURE* is affiliated with NPC. The *CURE* staff and the freelance writers hired by *CURE* are not employees, representatives, or associates of NPC. See Def. SUF at ¶¶ 89-100; cf., Pl. Resp. SUF at ¶¶ 86-100.

Although, as Plaintiffs point out, NPC sent published studies to the editor and publisher of *CURE* for use in an article on bisphosphonate therapy, Supplemental Certification of Michael

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[7] Ms. Bessemer claims that she may have read the following relevant articles appearing in *CURE*: "Myeloma 'Got Zometa?,'" by Amy D'Orazio, Spring 2002 (discusses Zometa® and Aredia®); Certification of Charles J. Falletta ("Falletta Cert."), Exh. 13, "The 15-Minute Bisphosphonate," by Amy D'Orazio, Summer 2002 (compares Aredia® to Zometa®); id. at 14, "Deep in the Bone: Managing Multiple Myeloma," by Faith Reidenbach, Summer 2002 (discusses bisphosphonates); id. at 15], "Stage 4: Expanding Options for Advanced," by Beverly A. Caley & Faith Reidbach, Fall 2003 (compares Aredia® and Zometa®); id. at 16, "Facing the Challenge – Spreading to the Bone," by Melissa Knopper (mentions Aredia® and Zometa®), Winter 2003; id. at 17, "What is Hypercalcemia of Malignancy," by Amy D'Orazio (mentioning Aredia® and Zometa®), Winter 2003; id. at 18. Ms. Bessemer does not specifically recall reading each and every one of these articles, 7/21/2010 Bessemer Dep. at 87:18-88:1, but claims that they were "in the mix of the materials [she] considered while taking Zometa® and made [her] more comfortable with taking it," Bessemer Cert. ¶ 11.

Two additional articles that mention Aredia® and Zometa®, appearing in the Winter 2004 issue of *CURE*, are not relevant in this case because the articles were published after Ms. Bessemer finished treatment with Aredia/Zometa®.

[8] As discussed in footnote 4, after additional discovery on this specific issue/theory, none of the authors were deposed to determine whether the authors were commissioned by NPC to write the articles.

Rosenberg in Opposition to Summary Judgment ("Rosenberg Supp. Summ. J. Cert."), Exh. 7 (email string between Susan McClure, *CURE*'s publisher, and Bruce Johnson, NPC's associate program project director for Zometa®), this does not amount to any express affirmation of fact or promise, or a description of the drug, by NPC to Ms. Bessemer. As the already-published and peer reviewed articles were not written by NPC or on behalf of NPC, they are not express warranties by NPC. Further, there is no indication as to what degree, if any, the already-published and peer reviewed articles were used in the bisphosphonate therapy article. Moreover, Plaintiffs have submitted no additional evidence to suggest that NPC employees had any involvement in writing any articles that appeared in *CURE*, nor that any NPC employees reviewed or edited the articles before they were published. Deposition of Bruce Johnson ("Johnson Dep.") at 140:12-20 (testifying that he had no involvement in drafting or reviewing any of the articles at issue). Plaintiffs have cited no law to support the notion that providing information to an author for use in an independently-drafted article or paying for advertising space in a magazine amounts to an express warranty. More importantly, Plaintiffs have failed to identify the affirmations of fact or promise or descriptions of the drug made by NPC to give rise to a breach of express warranty claim. For the foregoing reasons, summary judgment is granted as to Plaintiffs' breach of express warranty claim.

B. The DTC Exeeption to the Learned Intermediary Doctrine (PLA)

Plaintiffs also claim that NPC is not entitled to the benefit of the learned intermediary doctrine because NPC allegedly marketed Zometa® directly to Ms. Bessemer through magazine advertisements. Generally, under the New Jersey Products Liability Act, N.J.S.A § 2A:58C-1 et seq. (2010) ("PLA"):

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

New Jersey, like other jurisdictions, has adopted the learned intermediary doctrine, which recognizes ". . . 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 propensitics." Niemiera bv 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 thc characteristics of, and the ordinary knowledge common to, the preserihing physician," then a drug manufacturer will not be liable under the PLA. Niemiera, supra, 114 N.J. at 559.

Whilc a pharmaceutical manufacturer generally has no duty to warn the consumer directly under thc lcarned intermediary doctrine, the doctrine does not apply to "the direct marketing of drugs to consumers" where the consumer alleged that he or she was influenced by the advertising campaign for the drug. Perez v. Wyeth Lab., 161 N.J. 1, 14-15 (1999) (recognizing that there are "circumstances . . . in which the manufacturer should not be relieved of a duty to warn"). Perez, supra, 161 N.J. at 10. Thc Supremc Court of New Jersey adopted a DTC advertising exception to the learned intermediary doctrine, reasoning that, "[b]ecause situations may exist when the health-care provider assumes a 'much-diminished role as an evaluator or decision maker,' it is appropriate to impose a duty on the manufacturer to warn thc patient directly." Perez, supra, 161 N.J. at 14-15 (quoting Restatemcnt (Third) of Torts: Products Liability (1997), § 6d comment b).

The Perez Court held that "[p]reseription drug manufacturers that market their produets direetly to consumers should be subject to elaims by consumers if their advertising fails to provide an adequate warning of the product's dangerous propensities." Id. at 21. Where a patient is ". . . deprived of reliable medieal information . . ." through DTC advertising, he or she may maintain a DTC failure-to-warn elaim where ". . . the misinformation was a substantial factor eontributing to [the patient's] use of a defective pharmaceutical product." Id. at 31. In other words, a plaintiff cannot succeed under a DTC theory if the lack of information in the advertisement is not a "substantial faetor" in the plaintiff's decision to take, or continue to take, a drug. In the absenee of a DTC claim, the learned intermediary doctrine applies. A traditional failure-to-warn elaim under the PLA, rather than the DTC exception created by Perez, requires a plaintiff to show that this was a failurc to warn the plaintiff's treating physician.

Here, regardless of whether thc Zometa® advertisement appearing in *CURE* amounts to a DTC advertisement pursuant to Perez,[9] Plaintiffs' DTC claim fails because the *CURE* advertisement, and thus any alleged misinformation appearing in that advertisement, was not a substantial factor eontributing to Ms. Bessemer's use, or continued use, of Zometa®. See Perez, supra, 161 N.J. at 31. Ms. Bessemer does not claim to have seen the Zometa® advertisement until after she first started taking Zometa® in January 2002. Furthermore, Ms. Bessemer admitted in her deposition that "[n]othing in this advertisement" convinced her to continue to take Zometa®. 7/21/2010 Bessemer Dep. at 78:18-19.

While Ms. Bessemer stated that the advertisements, in tandem with the articles in *CURE*, played a role on her decision to eontinue taking Zometa®, such statements cannot overcome Ms.

[9] Defendant argues that the Perez exception to the learned intermediary doctrine does not apply to the facts of this case because the Zometa® advertisement does not qualify as the kind of mass marketiug campaign contemplated by Perez. Because Plaintiffs' DTC claim fails on other grounds, the court need not rule on this particular argument.

Bessemer's clear and unequivocal contrary response to defense counsel's direct question on the matter. See ibid. (affirming that "[n]othing in this advertisement" convinced her to continue to take Zometa). Nothing has been presented by Plaintiffs to convince a reasonable jury by a preponderance of the evidence that the one-page Zometa® advertisement (suggesting that she see her doctor about the drug) did, in fact, serve as a substantial factor in Ms. Bessemer's decision to use, or continued to use, Zometa®. See Brill, supra, 142 N.J. at 532 (quoting Improvement Co. v. Munson, 81 U.S. 442 (1872) (internal quotations omitted).[10]

Plaintiffs also argue that the DTC exception to the learned intermediary doctrine applies to this case because NPC, in addition to placing advertisements in *CURE*, influenced the editorial decisions of the magazine, even in issues where NPC placed no advertisements. Plaintiffs attempt to draw a connection between *CURE* and NPC beyond the advertising relationship. Plaintiffs describe how Amy D'Orazio ("Ms. D'Orazio"), author of several of the articles in *CURE* discussing Aredia/Zometa®, sought financial backing from NPC and met, called, and corresponded frequently with Bruce Johnson of NPC.

In late January 2004, Ms. D'Orazio, in her capacity as an employee of Physicians' Education Resource, LP ("PER") submitted a proposal to NPC's Bruce Johnson, seeking $519,500 in grant money, for the production of continuing medical education ("CME") materials for PER. See Rosenberg Supp. Summ. J. Cert., Exh. 14. Plaintiffs imply that this resulted in NPC having control over the content of the articles that Ms. D'Orazio wrote in *CURE*, and possibly other articles written in *CURE*. Plaintiffs also point to a March 31, 2004 letter from

[10] Moreover, Ms. Bessemer had nearly completed her course of treatment with Zometa® by the time she allegedly saw the Zometa® advertisement in the Winter 2003 issue of *CURE*. Ms. Bessemer's last dose of Zometa® was in April 2004. See Bessemer Cert. ¶ 9. Ms. Bessemer received only six infusions of Zometa® between Winter 2003 and April 2004, but had received 56 infusions of Aredia® and Zometa® prior to the advertisement's first appearance in *CURE*. Def. SUF at ¶ 6; Pl. Resp. SUF; Falletta Cert., Exh. 27. In light of these aforementioned facts, no reasonable jury could find that seeing one single-page advertisement in Winter 2003 was a "substantial factor" in Ms. Bessemer's decision to receive her last six infusions of Zometa®.

PER's Ms. D'Orazio to Bruce Johnson requesting $188,000 in grant money for PER. See Rosenberg Supp. Summ. J. Cert., Exh. 17.

However, the court does not find these facts to be persuasive or relevant. For one, there is no evidence that any money was actually given to PER or Ms. D'Orazio by NPC. Also, Bruce Johnson testified that when Ms. D'Orazio contacted him on this issue, she did so in her capacity as marketing director of PER. Johnson Dep. at 140:12-20. Plaintiffs have failed to establish that any grant to PER amounts to payment to *CURE* for the purpose of altering the content of the magazine in a way that amounts to DTC advertising under Perez. Further, these solicitations on behalf of PER were made in January and late-March 2004, after all relevant articles in *CURE* were published (Ms. Bessemer ceased taking Zometa® in April 2004, around the time that the Spring 2004 issue of *CURE* was published). If, assuming *arguendo*, the PER solicitation had any affect on the editorial content of *CURE*, it would have affected only content in those *CURE* magazines published after the Winter 2003 issue. The Spring 2004 issue contains no articles mentioning Zometa® and all subsequent issues were published after Ms. Bessemer received her last dose of Zometa®. Moreover, even if the court were to accept the notion that *CURE* altered the content of the magazine in favor of NPC to obtain money from NPC for PER, Plaintiffs have provided no legal support for the notion that this constitutes DTC advertising under Perez, thus giving rise to an exception to the learned intermediary doctrine.

Plaintiffs also explain how publishers and editors of *CURE* offered editorial support for Aredia/Zometa®, which was never explicitly disavowed by NPC employees. See Rosenberg Supp. SJ Cert., Exh. 7. Further, Plaintiffs contend that individuals quoted in the articles discussing Aredia®/Zometa® served as either experts for NPC in this litigation (Dr. Alan Lipton) or NPC consultants (Dr. Berensen and Dr. Durie). Despite Plaintiffs' allegations that

NPC had influence over the editorial decisions of *CURE*, Plaintiffs offer no evidence that NPC actually paid anyone at *CURE* to draft any articles or that NPC had any creative control over the content of the articles, even considering the affiliation between NPC and individuals quoted in the *CURE* artieles. According to the Perez decision, where "[p]rescription drug manufacturers [ ] market their products directly to consumers" the manufacture may be liable "if their advertising fails to provide an adequate warning of the product's dangerous propensities." Perez, supra, 161 N.J. at 21. The Perez decision is addressed to advertisements, not independently-drafted articles appearing in magazines in which pharmaceutical companies advertise. The court cannot expand Perez to independently-written articles appearing in magazines in which a pharmaceutical company advertises. Such a ruling would impose liability on pharmaceutical companies for the failure of a third-party to comply with FDA advertising regulations. See Perez, supra, 161 N.J. at 21-22, 24 (explaining that, "when prescription drugs are marketed and labeled in accordance with FDA specifications, the pharmaceutical manufacturers should not have to confront state tort liability premised on theories of design defect or warning inadequacy") (quoting Note, A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals, 103 Harv. L. Rev. 773 (1990)) (internal quotations omitted).

Therefore, the court grants summary judgment as to Plaintiffs' DTC advertising claim.[11] The learned intermediary doctrine shall apply to Plaintiffs' failure-to-warn claim under the PLA.

[11] Defendant also argues that a rebuttable presumption of adequacy should apply to the Zometa® advertisements because NPC complied with the FDA's requirements for advertisements. The court need not determine whether the advertisement at issue complies with the FDA's advertising regulations as Plaintiffs' DTC claim is rejected for other reasons specific to the facts in this case.

C. Defendant's Motion *In Limine* to Exclude Evidenee and Testimony

1. Aredia® Advertisements & Non-*CURE* Zometa® Advertisements

Defendant seeks to preclude Plaintiffs from offering testimony or evidenee regarding other advertisements plaeed by NPC in various caneer patient magazines. Between 1999 and 2004, NPC plaeed a number of advertisements for the drugs Aredia® and Zometa® in cancer patient-direeted magazines. Specifically, NPC placed a two page advertisement for Aredia® in *Coping with Cancer*, *MAMM*, and *InTouch*; two single-page advertisements for Zometa® in *CURE* or *MAMM*; and a single-page "advertorial" for Zometa® in *MAMM*. Defendant argues that reference to these advertisements as well as the Zometa® website should be excluded at trial. Defendant also seeks to prevent Plaintiffs from implying that NPC inappropriately influenced *CURE* articles that mention Aredia® or Zometa®.

Defendant argues that all advertisements for Aredia® should be excluded because Ms. Bessemer never claimed that she saw or relied on such advertisements while she was treated with Aredia®. In addition, Ms. Bessemer did not subscribe to the magazines in which Aredia® advertisements were placed. Defendant also urges exclusion of thc Zometa® advertorial for the same reason. Plaintiffs do not oppose this portion of NPC's motion, and therefore it is **GRANTED**. The parties are precluded from mentioning or referring to advertisements for Aredia®.

2. Zometa® Advertisements in *CURE* & Zometa® Website

Defendant also eontends that the Zometa® advertisements in *CURE* should be excluded because Ms. Bessemer did not see them prior to beginning her treatment with Zometa® and stated that she did not rely on those advertisements as part of her decision to take Zomcta®. As such, Defendant claims that the advertisements are irrelevant to the direct-to-consumer issues in

this case. See N.J.R.E. 401. Defendant also reasons that such evidence would be unduly prejudicial and create a risk of jury confusion under N.J.R.E. 403. Defendant further argues that testimony regarding the Zometa® website be excluded for the same reason.

Plaintiffs counter that Ms. Bessemer was convinced to maintain her Zometa® treatment after reading advertisements for Zometa® in *CURE*. Plaintiffs also argue that the articles and advertisements are relevant because they diluted the effectiveness of the warnings for Zometa®. In addition, Plaintiffs claim that Ms. Bessemer's testimony regarding the Zometa® website is relevant for the same reason.

While the court granted Defendant's motion for summary judgment on Plaintiffs' DTC advertising claims, the court must still examine the relevancy of the evidence for other purposes. Under N.J.R.E. 401, relevant evidence must have the tendency "to prove or disprove any fact of consequence to the determination of the action." In light of the court's determination that the DTC advertising exception in Perez is not present in this case, the advertisements placed in *CURE* magazine and Ms. Bessemer's testimony regarding the Zometa® website cannot be offered to abrogate the learned intermediary defense or to argue that Defendant was required to warn the consumer directly. Allowing the advertisements or website for either of these purposes would confuse the jury as to Defendant's duty to warn and have the potential to unduly prejudice Defendant. N.J.R.E. 403.

Plaintiffs also argue that the advertisements placed in *CURE* depicting a graphic of a femur ("bone advertisements") demonstrate NPC's manipulation of the post-marketing regulatory process through advertising, which would bear on the overall adequacy of the

Zometa® warning. Specifically, Plaintiffs elaim that NPC's decision to use a "reminder"[12] advertisement – after a previous advertisement depieting the frame of a house was rejeeted by the FDA's Division of Drug Marketing Advertising and Communications ("DDMAC") – is indieative of manipulation of the post-marketing regulatory proeess. Plaintiffs also elaim that NPC's use of the bone advertisements evidenees manipulation of the post-marketing regulatory process.

As to Plaintiffs' first argument, the court previously ruled in its Memorandum of Decision and Order on Defendant's Motion to Exclude the Testimony of Dr. Susan Parisian, dated April 30, 2010, that Plaintiffs are prohibited from offering evidence or testimony as to NPC's state of mind or intent. Plaintiffs' proffered evidence on NPC's advertising decisions is an impermissible attempt to bypass the court's ruling and will not be allowed at trial.

Plaintiffs' contention that a bone graphie in the Zometa® advertisements constitutes manipulation of the post-marketing regulatory proeess is unconvincing. MeDarby v. Merck & Co., Inc., 401 N.J. Super. 10 (App. Div. 2008) addressed an exception to the presumption of adequacy for FDA approved drugs where a manufacturer engaged in economically-driven efforts to dilute the effectiveness of a drug label or to otherwise inhibit the communication of newfound adverse information. The Appellate Division found that the inability of thc FDA "to detect unforeseen adverse effects of [a] drug and to take prompt and effective remedial action"

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[12] Reminder advertisemcnts are advertisements which call attention to the name of the drug product, but do not include information regarding indieations or dosage recommendations. 21 C.F.R. § 202.1(e)(2)(i). Reminder advertisements can only contain:

> [T]he proprictary name of the drug product, if any; the establishcd uame of the drug product, if any; the cstablished name of each active ingrcdient in the drug product; and, optionally, information relating to quantitative ingredient statements, dosage form, quantity of package contents, price, the name and address of the manufacturer, packer, or distributor or other written, printed, or graphic matter containiug no representation or suggestiou relating to the advertised drug product.
>
> [Ibid.]

Reminder advertisements are exempt from the requirement to display a statement of information relating to side effects, contraindications, and effectiveness. 21 C.F.R. § 202.1(e)(1)-(2).

following marketing approval provided an opportunity for drug manufacturers to avoid strengthening warnings when confronted with evidence of adverse events. Id. at 64. Specifically, the McDarby court held that a manufacturer's failure to investigate subsequently acquired information on health risks or to provide this information to prescribers bore on the adequacy of the warnings accompanying the drug. Id. at 68-69. Thus, the purpose of the McDarby exception was to ensure that pharmaceutical manufacturers investigated newly discovered risks regarding already approved drugs and communicated these risks to the FDA and prescribers.

The circumstances of this case are not analogous to McDarby. NPC submitted the bone advertisements published in *CURE* to the DDMAC for review. The DDMAC, a division of the FDA charged with reviewing advertisements, did not determine that the bone advertisements were improper. Plaintiffs provided no evidence that NPC's bone advertisements were intended to downplay the risks of Zometa® or had that effect. Indeed, the relevancy of the bone advertisements for such a purpose is questionable since the advertisements were directed to cancer patients, not prescribers, and contained no medical information or statements as to Zometa's® risks or benefits. Plaintiffs have neither argued nor offered any evidence that the bone advertisements for Zometa® or the Zometa® website influenced the decision of Ms. Bessemer's prescribing oncologist or had any bearing on the warnings at issue in this case. Zometa® was, and still is, prescribed to prevent the occurrence of skeletal related events, a fact which a prescribing oncologist would know even in the absence of a bone graphic. It is unlikely, if not impossible, that any physician would conclude from the presence of a femur in an advertisement targeted to cancer patients that "Zometa was good for bones and had limited side effects." As such, the bone advertisements for Zometa® and the Zometa® website have no

relevancy on whether Defendant adequately warned prescribing physicians. N.J.R.E. 401; State v. Wilson, 135 N.J. 4, 13 (2004) (evidence must have the tendency to "establish the proposition it is offered to prove.").

However, the court cannot exclude such evidence at this time since the evidence may be relevant to some other issue at the time of trial. Therefore, the court is unable to make such a blanket evidentiary ruling excluding all such evidence. Before offering any testimony or mention of advertisements, the court will require a proffer by the offering party. Thus, Defendant's motion to exclude evidence and testimony on the Zometa® advertisements and website is **GRANTED IN PART**.

3. Evidence Regarding the Relationship Between NPC & *CURE* Magazine

Defendant also seeks to preclude Plaintiffs from suggesting that NPC had a *quid pro quo* relationship whereby NPC would obtain both advertising and editorial exposure in *CURE* or that NPC inappropriately influenced the content of articles written about Aredia® and Zometa® that appeared in *CURE* magazine. According to Defendant, there is no indication that NPC was affiliated with the articles or played any role in the publication of the articles in *CURE*. Likewise, Defendant contends that Plaintiffs have produced no evidence of any influence by Defendant on the articles that Ms. Bessemer claims to have seen. Plaintiffs contest Defendant's characterization of the evidence and claim that e-mails exchanged between *CURE* staff and NPC employees demonstrate a mutual agreement between the two entities. Plaintiffs claim that the inability of either *CURE* or NPC to produce a document or contract signifying their agreement merits an adverse inference charge to be given to the jury by the court. Plaintiffs claim that e-mail communications between NPC and *CURE* employees and the absence of a document signifying their agreement is evidence of an improper relationship.

As indicated by the court earlier in this Memorandum of Decision, the court finds that Plaintiffs' evidence is nothing more than improper conjecture and innuendo. The court finds that there is no logical connection between the proffered evidence and what Plaintiffs seek to prove. See Furst v. Einstein Moomjy, Inc., 182 N.J. 1, 15 (2004); N.J.R.E. 401. To allow Plaintiffs to present evidence alluding to such a mutual relationship between NPC and *CURE* would result in jury confusion and would be prejudicial to Defendant, given the evidence's lack of probative value. See N.J.R.E. 403. As such, Defendant's motion to preclude Plaintiffs from implying that NPC inappropriately influenced articles published in *CURE* is **GRANTED**.

D. Defendant's Motion to Exclude Testimony of Plaintiffs' Expert Dr. Suzanne Parisian on the Issue of Direct-to Consumer Advertising

As Plaintiffs' breach of express warranty and DTC failure-to-warn claims fail for the reasons set forth in this Memorandum of Decision, Defendant's Motion to Exclude Testimony of Plaintiffs' Expert Dr. Suzanne Parisian on the Issue of Direct-to Consumer Advertising is **DENIED** as moot.

Jessica R. Mayer, J.S.C.