NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: FOSAMAX (ALENDRONATE SODIUM) PRODUCTS LIABILITY LITIGATION	
BARBARA GAYNOR and ROBERT GAYNOR, Plaintiffs, v. MERCK SHARP & DOHME CORP, Defendant.	Civil Action No. 12-1492, 08-08 **OPINION**

PISANO, District Judge

Plaintiffs Barbara and Robert Gaynor ("the Gaynor Plaintiffs") brought this lawsuit against Defendant Merck, Sharp, & Dohme Corp. ("Defendant" or "Merck"), the manufacturer of Fosamax, which is a drug approved by the United States Food and Drug Administration ("FDA") for the treatment and prevention of osteoporosis. This matter is part of the multi-district litigation ("MDL") concerning Fosamax and involves allegations that Fosamax causes atypical femur fractures ("AFFs[1]"), it caused Mrs. Gaynor's femur fracture, and Defendant failed to properly warn Mrs. Gaynor's physicians about Fosamax and AFFs. Presently before the Court is Defendant's Motion for Summary Judgment [docket #3152 in 08-08] and the Gaynor Plaintiffs' Motion for Discovery pursuant to Federal Rule of Civil Procedure 56(d) [docket #3541 in 08-08]. The parties have each opposed the respective motions [docket #3531 and

[1] The abbreviation of atypical femur fracture (singular) is "AFF."

#3825]. The Court considered the papers filed by the parties and rules on the written submissions without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, this Court grants Defendant's Motion for Summary Judgment and denies the Gaynor Plaintiffs' Motion for Discovery.

I. BACKGROUND

A. History of Fosamax

In September 1995, the FDA approved Fosamax for the treatment of osteoporosis in postmenopausal women, and in April 1997, the FDA approved Fosamax for the prevention of osteoporosis in postmenopausal women. See Declaration of Karen A. Confoy in Support of Merck's Motion for Summary Judgment ("Confoy Dec."), Exs. 1 and 2. Since this time, Fosamax has remained FDA approved for the treatment and prevention of postmenopausal osteoporosis. On June 13, 2008, the FDA contacted Defendant and other bisphosphonate[2] manufacturers and requested any investigations they conducted "regarding the occurrence of atypical fractures with bisphosphonate use," any investigational plans, and "all hip and femoral fracture case reports" they received. Confoy Dec., Ex. 3. The FDA also asked that Defendant and the other bisphosphonate manufacturers make an effort where possible "to clarify the fracture location and the duration of bisphosphonate exposure for all case reports." *Id.* The FDA explained that it was "aware of reports regarding the occurrence of subtrochanteric hip fractures in patients using bisphosphonates" and was "concerned about this developing safety signal." *Id.*

On July 18, 2008, Defendant responded to the FDA's request and included summary tables of clinical and post-marketing data, clinical Council for International Organizations of Medical Sciences ("CIOMS") reports, and post-marketing CIOMS reports. Confoy Dec., Ex. 4. The FDA's review of this data as well as the data from other bisphosphonate manufacturers "did

[2] Fosamax belongs to a class of drugs known as bisphosphonates.

not show an increase in . . . [the risk of atypical subtrochanteric femur fractures] in women using these medications" Confoy Dec., Ex. 7.

On September 15, 2008, Defendant submitted a Prior Approval Supplement ("PAS") to the FDA, proposing "to add language to both the Precaution[s] and Adverse Reactions/Post-Marketing Experience section[s] of the label to describe low-energy" subtrochanteric femoral fractures. Confoy Dec., Ex. 5. Defendant explained that "[i]t is not possible with the present data to establish whether treatment with" Fosamax "increases the risk of [these] . . . low-energy subtrochanteric and/or proximal shaft fractures," but because there was a temporal association between these fractures and Fosamax, Defendant thought that it was "important to include an appropriate statement about them in the product label." *Id.* Defendant sought to add the following language to the Precautions section of the label:

> Low-Energy Femoral Shaft Fracture
> Low-energy fractures of the subtrochanteric and proximal femoral shaft have been reported in a small number of bisphosphonate-treated patients. Some were stress fractures (also known as insufficiency fractures) occurring in the absence of trauma. Some patients experienced prodromal pain in the affected area, often associated with imaging features of stress fracture, weeks to months before a complete fracture occurred. The number of reports of this condition is very low, and stress fractures with similar clinical features also have occurred in patients not treated with bisphosphonates. Patients with suspected stress fractures should be evaluated, including evaluation for known causes and risk factors (e.g., vitamin D deficiency, malabsorption, glucocorticoid use, previous stress fracture, lower extremity arthritis or fracture, extreme or increased exercise, diabetes mellitus, chronic alcohol abuse), and receive appropriate orthopaedic care. Interruption of bisphosphonate therapy in patients with stress fractures should be considered, pending evaluation of the patient, based on individual benefit/risk assessment.
>
> *Id.*

Additionally, Defendant proposed adding "low-energy femoral shaft fracture" to the Adverse Reactions/Post-Marketing Experience section of the label and the following statement to the Patient Package Insert: "Patients have experienced fracture in a specific part of the thigh bone. Call your doctor if you develop new or unusual pain in the hip or thigh." *Id.*

On May 22, 2009, the FDA formally responded to Defendant's proposed label change, recommending that it add "low energy femoral shaft and subtrochanteric fractures" to the Adverse Reactions/Post-Marketing Experience section of the label; however, the FDA did not approve the label change to the Precautions section. Confoy Dec., Ex. 6. Moreover, the FDA warned that Fosamax "may be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act if [it is] . . . marketed with" these label changes "before [FDA] approval . . . ." *Id.* Thereafter, on March 10, 2010, the FDA issued a Drug Safety Communication, in which it stated that "[a]t this point, the data that [the] FDA has reviewed have not shown a clear connection between bisphosphonate use and a risk of atypical subtrochanteric femur fractures" Confoy Dec., Ex. 8. The FDA did state, however, that it was "working closely with outside experts, including members of the . . . American Society of Bone and Mineral Research Subtrochanteric Femoral Fracture Task Force, to gather additional information that may provide more insight into this issue." *Id.*

On September 14, 2010, the American Society for Bone and Mineral Research ("ASBMR") published an article entitled *Atypical Subtrochanteric and Diaphyseal Femoral Fractures: Report of a Task Force of the American Society for Bone and Mineral Research.* Confoy Dec., Ex. 9. The report stated that although there is an association between long-term bisphosphonate use and AFFs, the association has "not been proven to be causal." *Id.* at 2269, 2287. The report concluded that although AFFs are rare, "they appear to be more common in

patients who have been exposed to long-term BPs [("bisphosphonates")], usually for more than 3 years . . . ." *Id.* at 2287. The report further provided that although "BPs are important drugs for the prevention of common osteoporotic fractures," "atypical femoral fractures are of concern, and more information is urgently needed both to assist in identifying patients at particular risk and to guide decision making about duration of BP therapy. Physicians and patients should be made aware of the possibility of atypical femoral fractures and of the potential for bilaterality through a change in labeling of BPs." *Id.*

The FDA responded to the report by issuing a Drug Safety Communication, in which it stated "[a]lthough it is not clear if bisphosphonates are the cause [of AFFs], these unusual femur fractures have been identified in patients taking these drugs." Confoy Dec., Ex. 10. Additionally, the FDA informed that the "optimal duration of bisphosphonate treatment for osteoporosis is unknown" but "clinical trial data . . . support[s] effectiveness for the reduction of common bone fractures for three to five years." *Id.* Regarding the ASBMR Task Force's recommendation of a label change, the FDA stated that it "has assembled and is thoroughly reviewing all long term data available on the products, as well as all safety reports, and *is considering* label revisions." *Id.* (emphasis added).

In October 2010, the FDA issued another Drug Safety Communication, informing that it would require all bisphosphonate manufacturers to add information on AFFs to the Precautions section of the drug labels and require a new Limitations of Use statement in the Indications and Usage section of the label because "these atypical fractures may be related to long-term . . . bisphosphonate use." Confoy Dec., Ex. 11. It reiterated that "[a]lthough it is not clear if bisphosphonates are the cause, these unusual femur fractures have been predominantly reported in patients taking bisphosphonates." *Id.* On January 25, 2011, Merck incorporated the warning

concerning femur fractures to the Fosamax label in its Warnings and Precautions section. Under that heading, the label states: "Atypical Femur Fractures have been reported. Patients with new thigh or groin pain should be evaluated to rule out an incomplete femoral fracture." Confoy Dec., Ex. 13. Further, a sub-section of the label is devoted to "Atypical Subtrochanteric and Diaphyseal Femoral Fractures" and there, the label warns:

> Atypical, low-energy, or low trauma fractures of the femoral shaft have been reported in bisphosphonate-treated patients. These fractures can occur anywhere in the femoral shaft from just below the lesser trochanter to above the supracondylar flare and are transverse or short oblique in orientation without evidence of comminution. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with bisphosphonates.
>
> Atypical femur fractures most commonly occur with minimal or no trauma to the affected area. They may be bilateral and many patients report prodromal pain in the affected area, usually presenting as dull, aching thigh pain, weeks to months before a complete fracture occurs. A number of reports note that patients were also receiving treatment with glucocorticoids (e.g. prednisone) at the time of fracture.
>
> Any patient with a history of bisphosphonate exposure who presents with thigh or groin pain should be suspected of having an atypical fracture and should be evaluated to rule out an incomplete femur fracture. Patients presenting with an atypical fracture should also be assessed for symptoms and signs of fracture in the contralateral limb. Interruption of bisphosphonate therapy should be considered, pending a risk/benefit assessment, on an individual basis.
>
> Confoy Dec., Ex. 13.

In January 2011, Merck also modified the Medication Guide for Fosamax, which is included in the medication's tri-fold packaging, to expressly state that "FOSAMAX can cause serious side effects including . . . [u]nusual thigh bone fractures." Confoy Dec., Ex. 14. The Medication

Guide further explains that "[s]ome people have developed unusual fractures in their thigh bone. Symptoms of a fracture may include new or unusual pain in your hip, groin, or thigh." *Id.*

B. Procedural History and Mrs. Gaynor's Fosamax Use

Mrs. Gaynor began taking Fosamax in 1996 and was prescribed the drug by seven (7) different physicians until September 20, 2011, when she sustained a right spontaneous atypical femur fracture. Plaintiffs' Rule 56.1 Statement in Support of Plaintiffs' Memorandum of Law in Opposition to Defendant Merck Sharp & Dohme Corp.'s Motion for Summary Judgment ("Plaintiffs' Statement of Fact"), ¶¶ 43, 49. On March 9, 2012, the Gaynor Plaintiffs filed a Complaint against Merck claiming that Mrs. Gaynor's long-term use of Fosamax caused her to suffer a femur fracture.

The Gaynor Plaintiffs' Complaint asserts thirteen (13) causes of action against Merck: (1) failure to warn under the New Jersey Product Liability Act ("NJPLA") or New York law; (2) defective design under the NJPLA or New York law; (3) strict liability if New York law applies; (4) negligence if New York law applies; (5) negligent misrepresentation if New York law applies; (6) breach of express warranty; (7) breach of the implied warranty of fitness for a particular purpose; (8) breach of the implied warranty of merchantability; (9) New Jersey Consumer Fraud Act ("NJCFA"); (10) New York General Business Law; (11) unjust enrichment; (12) punitive damages; and (13) loss of consortium [docket #1 in 12-1492].

The Gaynor Plaintiffs have been categorized as a "post-label change" case because Mrs. Gaynor's injury occurred after September 14, 2010. Throughout this MDL, the parties and the Court have been categorizing cases as either "pre-label change" or "post-label change." In April 2013, this Court tried the case of Plaintiff Glynn, a pre-label change case, as its first Bellwether and ultimately granted judgment as a matter of law in favor of Merck on federal preemption

grounds. See *Glynn v. Merck Sharp & Dohme, Corp.*, Case Nos. 11-503, 08-08, --- F. Supp. 2d ---, 2013 WL 3270387 (D.N.J. Jun. 27, 2013). Thereafter, this Court ordered all other Plaintiffs whose injuries occurred prior to September 14, 2010, to show cause why their claims were not preempted pursuant to the *Glynn* ruling [docket #2895]. On March 26, 2014, this Court granted judgment in favor of Merck on all pre-label change cases, holding that such Plaintiffs claims were preempted as a matter of law because clear evidence existed that the FDA would not have approved a stronger warning label as of the date of their injuries. See *In re Fosamax (Alendronate Sodium): Products Liab. Litig.*, MDL 2243, 2014 WL 1266994 (D.N.J. Mar. 26, 2014).

While a significant amount of time and resources have been spent focusing on the preemption issue as it relates to pre-label change cases, the parties and the Court have also been mindful of the post-label change cases, the theories of liability involved therein, and how to address these cases. In fact, all counsel were in agreement that after *Glynn*, the next Bellwether would be a post-label change case in order to test the adequacy of the Fosamax label. The parties and the Court were operating under the assumption that Plaintiffs' failure to warn claims were either: (1) pre-label change cases based on Merck's failure to update the Fosamax label prior to January 2011; or (2) post-label change cases based on the ultimate content and adequacy of the label itself. At a July 18, 2013, status conference the Court specifically asked Plaintiffs' counsel:

> THE COURT: What's the theory? How would you try a post-label change case? . . . What's the claim?
>
> MR MORRIS: **We would still argue that the current label is insufficient.** First of all, it doesn't say anything about duration. It gives some discussion about maybe you should have a drug holiday after five years, but it doesn't say anything about what the causal relevance would be.
>
> THE COURT: Okay. So that's a whole different liability theory?

MR MORRIS: Yes, sir.

[docket #2998, *Hearing Tr.*, 17:21-18:7; July 18, 2013 (emphasis supplied)].

The next Bellwether trial was scheduled to begin in January 2014; however, it appeared to the Court that the Plaintiff chosen for this Bellwether, Mrs. Zessin, presented a pre-label change case and therefore a trial would not resolve whether the revised warning label was adequate as a matter of law. Thus, on July 26, 2013, Merck suggested that Mrs. Gaynor be replaced as the Bellwether Plaintiff for January 2014 because she suffered a post-label change injury and would permit the parties to address whether the warnings provided by Merck were adequate [docket #2846]. The only objection made by Plaintiffs to this proposal was "disagree[ing] with Merck's position that the Gaynor case (or any other post-label change case) c[ould] be ready for trial by January 2014." [docket #2880]. Further, Plaintiffs submitted that it would be more appropriate to develop a Bellwether selection process for the parties to have sufficient time to prepare because "[m]any of the cases involving post-September 14, 2010 injuries [were] in the early stages of discovery and, like Barbara Gaynor, lack[ed] complete medical records [which] . . . generally take[] 90 to 120 days to obtain. . . ." [docket #2880].

As such, the Court pushed the Bellwether trial date to May 2014, and on September 23, 2013, ordered the parties to each identify two (2) cases that allege a post-label change injury, with case specific fact discovery in those four (4) cases to be completed by December 16, 2013. [docket #2917]. On September 27, 2013, Merck identified its two (2) cases, one of which still being Mrs. Gaynor. [docket #2933]. By the close of case specific fact discovery, the four (4) cases from which to select the next Bellwether were Plaintiffs Gaynor, Bednar, Mercer, and Sweet. [docket #3095]. The parties each submitted recommendations to this Court about which Plaintiff should be selected as the Bellwether. On December 20, 2013, the Court conducted a

telephone conference with the parties and ultimately selected Plaintiff Sweet as the May 2014 Bellwether case.[3] [docket #3104]. Shortly thereafter, however, Plaintiff Sweet voluntarily dismissed her case against Merck. [docket #18 in 12-3590]. Similarly, Plaintiff Bednar had dismissed her case against Merck. [docket #12 in 13-65]. Thus, Mrs. Gaynor was the only remaining Plaintiff; however, Plaintiffs' counsel objected to her being the May 2014 Bellwether because it was unclear whether she suffered a qualifying fracture.

On January 29, 2014, the parties appeared before the Court for oral argument on the OTSC and also discussed how to proceed with the post-label change cases. Despite issues surrounding whether Mrs. Gaynor suffered a qualifying fracture, the Gaynor Plaintiffs indicated that they would not be dismissing their claims against Merck, but still insisted that this case not proceed to trial. Merck advised Plaintiffs' counsel and the Court that, if the Gaynor Plaintiffs were not going to dismiss their claims, Merck was prepared to move for summary judgment within thirty (30) days because the Gaynor Plaintiffs presented a post-label change case permitting this Court to determine whether the Fosamax label was adequate as a matter of law. Merck also insisted that Mrs. Gaynor remain on the calendar as the May 2014 Bellwether because if summary judgment was unsuccessful, Defendant was prepared to try the case. The Court agreed to allow a dispositive motion to be filed in order to address the adequacy of the label, but instructed the parties to each identify five (5) post-label change cases for expedited fact discovery, one of which would be tried as the next Bellwether in October 2014. [docket #3147]. Plaintiffs made no objections to this approach.

As the parties began identifying five (5) cases for expedited fact discovery, and after adjourning the trial date twice, Plaintiffs' position on having a post-label change Bellwether trial

[3] The Court also determined that Plaintiff Mercer would be an improper Bellwether because she did not ingest Fosamax after the date of the label change and therefore, her case would present issues in determining whether the label was adequate.

drastically changed. Instead, Plaintiffs contended that the Court's proposed schedule to conduct a post-label change Bellwether trial in October 2014 was moot because "no Plaintiff alleges that the January 2011 label was a proximate cause of his or her injury." [docket #3147]. Further, Plaintiffs wrote to this Court on February 28, 2014 – thirty (30) days after the parties last appeared before the Court and the same date Merck indicated it would be filing its motion for summary judgment – suggesting that Mrs. Gaynor would not be alleging that the label was a proximate cause of her injuries and therefore making a motion for summary judgment "would be a waste of resources for all concerned." [docket #3151]. On this same day, Merck filed its motion for summary judgment. [docket #3152].

Shortly thereafter, Plaintiffs again wrote to this Court requesting a conference suggesting that, because Mrs. Gaynor's case was no longer scheduled to proceed to trial, requiring Plaintiffs to engage in discovery in order to oppose Merck's summary judgment motion would be "a wasteful burden on the Plaintiffs" and therefore, Plaintiffs "suggest[ed] the defense withdraw their motion." [docket #3165]. In light of this, the Court conducted a telephone conference with the parties on March 26, 2014, to address the post-label change cases and advised the parties that it intended to move forward on deciding Merck's motion for summary judgment. [docket #3204]. Further, given Plaintiffs' representation that it did not have a Bellwether Plaintiff, the Court canceled the October 2014 trial date. Thus, Plaintiffs indicated that they would file an opposition to Merck's motion [docket #3531] to which Merck replied [docket #3821].

II. DISCUSSION

A. Motion for Summary Judgment - Legal Standard

Federal Rule of Civil Procedure 56(a) provides that "a court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The substantive law identifies which facts are material. "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). A material fact raises a "genuine" issue "if the evidence is such that a reasonable jury could return a verdict" for the non-moving party. *Healy v. N.Y. Life Ins. Co.,* 860 F.2d 1209, 1219 n. 3 (3d Cir.1988).

The Court must consider all facts and their logical inferences in the light most favorable to the non-moving party. *Pollock v. Am. Tel. & Tel. Long Lines,* 794 F.2d 860, 864 (3d Cir.1986). The Court shall not "weigh the evidence and determine the truth of the matter," but need determine only whether a genuine issue necessitates a trial. *Anderson,* 477 U.S. at 249. While the moving party bears the initial burden of showing the absence of a genuine issue of material fact, meeting this obligation shifts the burden to the non-moving party to "set forth specific facts showing that there is a genuine issue for trial." *Id.* at 250. If the non-moving party fails to demonstrate proof beyond a "mere scintilla" of evidence that a genuine issue of material fact exists, then the Court must grant summary judgment. *Big Apple BMW v. BMW of N. Am.,* 974 F.2d 1358, 1363 (3d Cir.1992).

B. The Gaynor Plaintiffs' Failure to Warn Claim

The Gaynor Plaintiffs' failure to warn claim is based on the allegation that Fosamax "was not accompanied by appropriate warnings" because "[t]he warnings given did not adequately reflect the risk" of suffering an AFF [docket #1 in 12-1492, at ¶ 69]. Further, the Gaynor Plaintiffs allege that "Defendant failed to timely and reasonably warn [Mrs. Gaynor] and [Mrs.

Gaynor's] prescribing physicians of material facts regarding the comparative safety and efficacy of Fosamax." [docket #1 in 12-1492, at ¶ 71]. Merck contends that the Gaynor Plaintiffs' failure to warn claim fails because Fosamax contained a label expressly warning of the type of harm suffered by Mrs. Gaynor and that such label was adequate as a matter of law.

As outlined above, Plaintiffs with post-label change cases have tactfully re-characterized their failure to warn claims throughout the progression of this MDL and the Gaynor Plaintiffs are no exception. While the Gaynor Plaintiffs' Complaint specifically alleges that the warnings given by Defendant were not adequate, they are now contending that this Court should not determine whether the Fosamax label is adequate because Mrs. Gaynor is not contending that the label was a proximate cause of her injury [docket #3165]. Plaintiffs cannot have it both ways. It is axiomatic that an essential element of a failure to warn claim is a defendant's failure to adequately warn about the alleged risks associated with its product. *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009). Thus, Plaintiffs' claim must be based on some alleged failure by Merck. The Gaynor Plaintiffs have spent a considerable amount of time pointing out to the Court what they are *not* basing their failure to warn claim on – such as, the adequacy of the label – but have hardly presented evidence on what they *are* basing this claim on.

In order to maintain a failure to warn claim under New York law[4], "[a] plaintiff must show a breach of the duty to warn and 'that the failure to warn was the proximate cause of his [or her] injury.'" *Saladino v. Stewart & Stevenson Servs., Inc.*, 704 F. Supp. 2d 237, 249 (E.D.N.Y. 2010) (quoting *Henry v. Rehab Plus Inc.*, 404 F.Supp.2d 435, 442 (E.D.N.Y.2005)). In order to establish proximate cause, a plaintiff must show that a defendant's conduct was a substantial factor in bringing about the injury. *Id.* The Gaynor Plaintiffs contend that an issue of fact exists

[4] The parties agree that New York law governs the Gaynor Plaintiffs' substantive claims.

surrounding the adequacy of the label because "Merck has submitted no evidence that [Mrs. Gaynor's] use of Fosamax in 2011 was a substantial factor in causing [Mrs. Gaynor's] femur fracture." [docket #3531, at p. 10]. In making this argument, the Gaynor Plaintiffs are confusing the appropriate analysis when adjudicating a failure to warn claim by expecting Merck to *first* prove that no issue of fact exists surrounding *proximate cause*; however, if Merck meets its burden by showing that no issue of fact exists surrounding a *breach* – the proximate cause analysis is irrelevant. *Mustafa v. Halkin Tool, Ltd.*, 00-CV-4851 (DGT), 2007 WL 959704, at *17 (E.D.N.Y. Mar. 29, 2007) ("[A] failure to warn claimant must show: 1) the manufacturer had a duty to warn; 2) the duty to warn was breached; and 3) the failure to warn was a substantial or proximate cause of the harm.") (citing *Clarke v. LR Sys.*, 219 F.Supp.2d 323, 331 (E.D.N.Y.2002)).

The Gaynor Plaintiffs appear to base their failure to warn claim on two (2) theories. The first is Defendant's failure to "timely" warn, and/or that Merck should have updated its label sooner, by arguing that the 2011 label is not relevant to Mrs. Gaynor's claim because her injuries were fait accompli by the time the 2011 label was updated. In support of this theory, the Gaynor Plaintiffs contend that they "intend to prove that by the late-1990's and early-2000's, Merck knew or should have known of the risk of spontaneous atypical femur fracture[s] related to Fosamax based upon pre-clinical investigation into the drug . . . and evidence received by Merck after the drug was released on the market" and that "[t]his evidence should have compelled Merck to update the Fosamax label to warn of the risk of spontaneous femur fracture[s] by the mid-2000's, or earlier." [docket #3531, at pp. 9-10]. Plaintiffs also assert that summary judgment is improper because the adequacy of the label is not at issue since Merck has submitted no evidence that Mrs. Gaynor's "use of Fosamax from 1996 through 2010 [(or, prior to the label

change)] was not a substantial factor in causing her injury." [docket #3531, at p. 10]. This position is baffling, because if the Gaynor Plaintiffs are basing their failure to warn claim on Merck's conduct between 1996 and 2010, or the fact that Merck should have updated its label by the mid-2000's at the latest, then this Court has already held – twice – that such failure to warn claim fails as a matter of law on preemption grounds. See *In re Fosamax,* 2014 WL 1266994; *Glynn,* 2013 WL 3270387.

Alternatively, the Gaynor Plaintiffs argue that while the actual content of the Fosamax label was not a proximate cause of Mrs. Gaynor's injuries, Merck's alleged failure to communicate the risks to Mrs. Gaynor's prescribers following the label revision forms the basis of this claim. As an initial matter, Plaintiffs' two (2) arguments are inconsistent. In the first instance, the Gaynor Plaintiffs' expert, Dr. Charles Cornell opined that ". . .even if Mrs. Gaynor had been taken off Fosamax by February 2011, she still would have had severely compromised femoral bone due to her pre-2011 prolonged Fosamax use." See Declaration of Edward Braniff, at Ex. 1 ¶ 20. Stated differently, Plaintiffs on the one hand argue that Merck's alleged failure to communicate risks of an AFF following the label revision in January 2011 is a proximate cause of Mrs. Gaynor's injuries, and on the other hand claim that this Court should not address the adequacy of the label at all because even if she stopped taking Fosamax by the date of the label revision – or in other words, the date Merck would have communicated such risks to Mrs. Gaynor's physicians – she still would have been injured. One argument focuses on proximate cause without addressing a breach and the second focuses on breach without addressing proximate cause.

The Gaynor Plaintiffs are attempting to link long-term ingestion of Fosamax to Mrs. Gaynor's injury as a means of establishing proximate cause. However, the causation analysis

must link Mrs. Gaynor's injury to a breach or alleged failure by Merck. The only two (2) possible breaches alleged by the Gaynor Plaintiffs are: (1) Merck's failure to update its label by the early-2000's; and/or (2) Merck's failure to communicate the January 2011 revised warning label to Mrs. Gaynor's prescribing physicians. As set forth above and stated by this Court previously, the first alleged breach cannot form the basis of the Gaynor Plaintiffs' failure to warn claim because clear evidence exists that the FDA would have rejected a stronger warning label prior to September 14, 2010. *In re Fosamax*, 2014 WL 1266994; *Glynn*, 2013 WL 3270387; *Wyeth v. Levine*, 555 U.S. 555 (2009). Further, the Gaynor Plaintiffs' second theory also fails as a matter of law because there can be no proximate cause connected to this alleged breach when the Gaynor Plaintiffs' own expert concludes that, regardless of whether the label was updated in 2011 – and accordingly, whether such revision was communicated to Mrs. Gaynor's physicians – Mrs. Gaynor still would have suffered an injury. See *Hutton v. Globe Hoist Co.*, 158 F. Supp. 2d 371, 375 (S.D.N.Y. 2001) (holding that plaintiff's failure to warn claim was precluded under New York law because failure to warn was not proximate cause of injury). Simply put, even assuming Merck breached a duty, if the alleged breach occurred in 2010 or earlier, the Gaynor Plaintiffs' claims are preempted, and if the alleged breach occurred in 2011 or later, then no proximate cause exists linking such breach to Mrs. Gaynor's injury as indicated by Plaintiffs' own expert.

Moreover, the Court disagrees with Plaintiffs that determining the adequacy of the Fosamax label is not ripe. Merely because the Gaynor Plaintiffs have, at the last hour, conveniently chosen not to challenge the adequacy of the label as part of their failure to warn claim, the Gaynor Plaintiffs' Complaint specifically alleges that the label is inadequate and the inquiry is relevant to the Courts analysis in determining whether Merck breached any duty.

DiBartolo v. Abbott Labs., 914 F. Supp. 2d 601, 613 (S.D.N.Y. 2012) (". . . [A] court deciding a failure-to-warn claim under New York law must consider not merely the existence of a relevant warning, but also the qualitative adequacy of that warning.").

In determining whether an issue of fact exists surrounding the adequacy of a warning, "New York courts 'evaluate the [warning]'s language for its accuracy, clarity and relative consistency.'" *Id.* at 612 (quoting *Martin v. Hacker*, 83 N.Y.2d 1, 11, 628 N.E.2d 1308, 1313 (1993)). The first element, accuracy, is satisfied where a warning is "'correct, fully descriptive and complete, and … convey[s] updated information as to all of the drug's known side effects.'" *Id.* Second, a warning is clear if "it employs language that is 'direct, unequivocal and sufficiently forceful to convey the risk.'" *Id.* Third, relative consistency requires the Court to examine whether an otherwise clear warning is "obscured by inconsistencies or contradictory statements made in different sections of the package insert regarding the same side effect or from language in a later section that dilutes the intensity of a caveat made in an earlier section." *Id.* In making this determination, however, a warning with such contradictions may still be adequate "'if the language of a particular admonition against a side effect is precise, direct, and unequivocal and has sufficient force.'" *Id.* (citing *Martin*, 83 N.Y.2d at 12). Last, a court will evaluate the warning as a whole because any vagueness appearing from the individual sentences read in isolation "may be overcome if, when read as a whole, the warning conveys a meaning as to the consequences that is unmistakable." *Id.*

Further, New York "has adopted the Informed Intermediary Doctrine ("IID"), also known as the Learned Intermediary Doctrine, which provides that a drug manufacturer's duty is to warn the treating physician, not the patient." *Id.* (citing *Martin*, 83 N.Y.2d at 9). Here, the parties do not dispute whether Merck had a duty to warn Mrs. Gaynor directly; however, the Gaynor

Plaintiffs contend that issues of fact exist as to whether Merck properly communicated the revised warning label to Mrs. Gaynor's prescribing physician(s). It is axiomatic that, in order to determine whether the IID is satisfied and whether summary judgment is proper, the Court must determine if the warning label itself is adequate as a matter of law as it regards AFF's.

First, the Fosamax label is accurate. There have been no allegations that the label contains incorrect information and further, the label is fully descriptive, complete, and conveys updated information as to Fosamax's side effects surrounding AFF's. The label warns of AFF's in both the Adverse Reactions and the Warnings and Precautions sections, and an entire sub-section is even devoted to "Atypical Subtrochanteric and Diaphyseal Femoral Fractures." Confoy Dec., Exs. 13-14. Second, the language employed on the warning label is sufficiently clear as it is direct and unequivocal and sufficiently conveys the risk of AFF's when taking Fosamax. Third, the sections and subsection of the Fosamax label which contain warnings related to AFF's, as well as the Medication Guide directed towards patients, are consistent and precise, without any contradictions. As a whole, the label conveys an unmistakable meaning as to the consequences of ingesting Fosamax and instead of simply stating that a side effect may result from use of the drug, it advises physicians of the specific manner in which an AFF may materialize. *DiBartolo*, 914 F. Supp. 2d at 612 (indicating that an important principle when determining whether a prescription drug warning label is adequate is analyzing whether a warning advises physicians of the specific manner in which the risk of that side effect will materialize). Thus, in finding that the label is accurate, clear, consistent and as a whole conveys a meaning that is unmistakable as it relates to AFF's, the Court is satisfied that the Fosamax label is adequate as a matter of law. See *Martin v. Hacker*, 83 N.Y.2d 1, 12, 628 N.E.2d 1308, 1313

(1993) (finding that a warning is adequate when "read as a whole, the warning conveys a meaning as to the consequences that is unmistakable.").

Further, the Gaynor Plaintiffs have failed to set forth sufficient evidence showing that a material fact dispute exists regarding whether Defendant communicated these warnings to Mrs. Gaynor's prescribing physicians such that the IID is not satisfied. Plaintiffs contend that this is a "no warning case" because Merck failed to communicate the content of the revised warning label to Mrs. Gaynor's prescribing physicians, thereby breaching its duty to warn. In support of this theory, however, Plaintiffs merely advance evidence of when Mrs. Gaynor's prescribing physicians recall learning about the revised Fosamax label, not whether or when Merck actually communicated these risks. The record demonstrates that Merck adequately communicated the 2011 warning. See Confoy Dec., Ex. 16 (February 3, 2011 "Dear Colleague" letter dispersed to physicians expressly stating that the prescribing information for Fosamax has been updated and including both the new warnings and the stricken language in full); Merck's Statement of Facts, ¶ 8 (explaining Merck's modification of the patient-directed Medication Guide); Confoy Dec., Ex. 17 (demonstrating that Merck trained its sales representatives to proactively communicate the Fosamax label changes); Confoy Dec., Ex. 18 (January 28, 2011 email confirming that the merck.com website had been updated with the January 2011 Fosamax Prescribing Information); Confoy Dec., Ex. 19 (demonstrating that Merck updated the discussion of Fosamax in the Physicians' Desk Reference at the next available publication).

Plaintiffs contend that Mrs. Gaynor's physician, Dr. DiGiovanna, may not have received the Dear Colleague letter because she could not recall the precise date on which she first learned that the 2011 Fosamax label was revised and could not agree that she was aware of the label change in 2011 when she last refilled Fosamax prescriptions for Mrs. Gaynor. See Declaration

of Edward Braniff, Ex. 55 ("DiGiovanna Dep.") at 149:6-10; 113:9-20. However, this testimony does not raise an issue of fact on Merck's adequacy in communicating the warnings to Dr. DiGiovanna. Rather, Merck has demonstrated that it utilized several avenues to communicate the revised warning label and further, Dr. DiGiovanna's testimony reveals that she does recall becoming aware of the new information in 2011, she was just uncertain whether it was from a letter or not. DiGiovanna Dep., 110:3-9. The IID analysis is not dependent on *how* Dr. DiGiovanna learned of the revised label, but instead is determined by *if* she did. The record is devoid of any factual disputes surrounding whether Dr. DiGiovanna was made aware of the label change and therefore, the IID is satisfied here. See DiGiovanna Dep., 109:12-110:2 (where Dr. DiGiovanna acknowledges that she was listed as a recipient of Merck's February 2011 email communicating the revised label).

Last, Merck has demonstrated that the Fosamax label expressly warned of the precise injury that Mrs. Gaynor suffered, and that the content of the label contains the exact language required by the FDA. As such, Merck is entitled to summary judgment on the Gaynor Plaintiffs' failure to warn claim. See *In re Accutane Products Liab. Litig.*, 2012 WL 3194954, at *5 (M.D. Fla. July 24, 2012) ("It has long been the law in New York that prescription medicine warnings are adequate when, as here, information regarding the 'precise malady incurred' was communicated in the prescribing information. *Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 423 N.Y.S.2d 95, 96-97 (N.Y. App. Div. 1979), *aff'd*, 52 N.Y.2d 768, 436 N.Y.S.2d 614, 417 N.E.2d 1002 (N.Y. 1980); *Fane v. Zimmer*, 927 F.2d 124, 129 (2d Cir. 1991). In such instances, when a plaintiff claims to be injured in a manner that is addressed by warnings provided to his physician, summary judgment is granted on failure to warn claims." See, e.g., *Sita v. Danek Medical Inc.*, 43 F.Supp.2d 245, 260 (E.D.N.Y. 1999) (citing *Alston*, 670 F.Supp.2d at 284-85)).

C. The Gaynor Plaintiffs' Remaining State Law Claims[5]

Defendant argues that it is entitled to summary judgment on the Gaynor Plaintiffs' remaining claims because they are predicated on a failure to warn. The Court agrees that, under New York law, the adequacy of the Fosamax warning label, as a matter of law, precludes any related claims for negligence, strict liability, breach of warranties, or fraud. See *In re Accutane*, 2012 WL 3194954, at *6 (citing *Martin*, 607 N.Y.S.2d 598, 628 N.E.2d at 1311, n. 1 ("[w]here liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent"). Here, the Gaynor Plaintiffs' claims for design defect, negligence, strict liability, and breach of warranties are directly related to the warning label. Compl. ¶ 93 ("Fosamax, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendant was defective due to inadequate warnings and instructions."); Compl. ¶ 106(d) ("Defendant failed to warn and place adequate warnings and instructions on Fosamax."); Compl. ¶ 112(d) (Alleging that Defendant was negligent for "[f]ailing to warn Plaintiff, the medical and healthcare community, including [Mrs. Gaynor's] physicians, the general public, or the FDA, as soon as Defendant knew or should have known of the dangers of the use of Fosamax. . . ."); Compl. ¶ 122 ("As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendant . . . Defendant knew, and had reason to know, that Fosamax . . . lacked adequate and accurate warnings. . ."); Compl. ¶ 127 (Alleging that Fosamax causes the ". . . very fractures that Defendant expressly warranted Fosamax to prevent, of which Defendant did not accurately warn about . . .").

Further, even assuming that the Gaynor Plaintiffs' design defect claim was unrelated to the warning label, such claim still fails as a matter of law because New York law is clear that,

[5] The Gaynor Plaintiffs voluntarily withdrew their claims pursuant to the New Jersey Consumer Fraud Act, unjust enrichment, and the New York General Business Law. As such, the Court will not address these causes of action.

where a prescription drug is accompanied by a proper warning, such product is not defective nor is it unreasonably dangerous. *Id.* at *6 (quoting *Martin,* 607 N.Y.S.2d 598, 628 N.E.2d at 1311). Similarly, Plaintiffs' warranty and negligent misrepresentation claims fail for independent reasons as the Gaynor Plaintiffs have failed to show that Merck made any warranty or misstatement to Mrs. Gaynor or her prescribing physician(s). See *Fisher v. APP Pharm., LLC*, 783 F. Supp. 2d 424, 432 (S.D.N.Y. 2011) ("Plaintiff's failure to allege any specific words, promises or statements made by [defendants] to [decedent] or his physicians that would create an express warranty is fatal to the claim."); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 260 (E.D.N.Y. 1999) (granting Defendant's motion for summary judgment on a negligent misrepresentation claim where "there [was] no proof of a specific false statement, much less an intentionally false statement, made by [defendant's] representatives upon which either plaintiff or [plaintiff's physician] relied . . ."). Accordingly, for the reasons set forth above, the Gaynor Plaintiffs' second cause of action for defective design, third cause of action for strict liability, fourth cause of action for negligence, fifth cause of action for negligent misrepresentation, sixth cause of action for breach of express warranty, seventh cause of action for breach of the implied warranty of fitness for a particular purpose, and eighth cause of action for breach of the implied warranty of merchantability fail as a matter of law and Defendant is entitled to summary judgment on these claims.[6]

D. Motion for Discovery – Legal Standard

[6] The Gaynor Plaintiffs' remaining claims for loss of consortium and punitive damages are derivative of Plaintiffs' other causes of action. See *Delehanty v. KLI, Inc.*, 663 F. Supp. 2d 127, 134 (E.D.N.Y. 2009) ("A claim for loss of consortium is derivative of the underlying claims. Thus, under New York law, Mrs. Delehanty's claim must also be dismissed because Mr. Delehanty's causes of action fail."). Accordingly, these claims must also fail as a matter of law.

Rule 56(d) authorizes a court to defer or deny a summary judgment motion where the nonmoving party shows "by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition." Fed. R. Civ. P. 56(d). "In opposing a summary judgment motion on the ground that there was an insufficient opportunity to conduct discovery, a litigant is required to submit an affidavit that includes: '[(1)] the nature of the uncompleted discovery; [(2)] how the facts sought are reasonably expected to create a genuine issue of material fact; [(3)] what efforts the affiant has made to obtain those facts; and [(4)] why those efforts were unsuccessful.'" *Hoffmann v. Airquip Heating & Air Conditioning*, 480 F. App'x 110, 111-12 (2d Cir. 2012) (quoting *Paddington Partners v. Bouchard*, 34 F.3d 1132, 1138 (2d Cir.1994)). Further, "[r]elief under Rule 56(d) 'is not available when summary judgment motions are made after the close of discovery.'" *Capitol Records, Inc. v. MP3tunes, LLC*, 07 CIV. 9931 WHP, 2013 WL 1987225 (S.D.N.Y. May 14, 2013) (quoting *Espada v. Schneider*, 522 F.Supp.2d 544, 549 (S.D.N.Y.2007)).

E. Analysis

The Gaynor Plaintiffs argue that additional discovery is necessary in order to oppose Defendant's summary judgment motion. While this request is now moot, for purposes of completeness the Court will address it. Plaintiffs submit that they were unaware Merck intended to move for summary judgment on all of Plaintiffs' claims and, because Mrs. Gaynor was not selected as the next Bellwether, decided not to conduct discovery. As an initial matter, general discovery in this MDL closed more than a year ago and case-specific fact discovery closed more than six (6) months ago on December 16, 2013. [docket #2919]. Plaintiffs were aware that Merck intended to move for summary judgment in Mrs. Gaynor's case; therefore, the failure to

conduct any discovery which may be relevant in opposing such a motion is no fault other than Plaintiffs' own.

The declaration submitted in support of Plaintiffs' motion addresses the nature of the uncompleted discovery, but fails to demonstrate how such discovery would create a genuine issue of fact or what efforts have been made by Plaintiffs' counsel to obtain these facts. Deposing every physician who prescribed Mrs. Gaynor Fosamax will not change Plaintiffs' expert, Dr. Cornell's opinion that, regardless of the label change, Mrs. Gaynor would have still suffered an injury in 2011. As such, the depositions or outstanding discovery would not create an issue of fact as to whether Mrs. Gaynor's claim is preempted or whether Merck's label is adequate as a matter of law, and Plaintiffs' request must be denied. See *Betances v. Prestige Decorating & Wallcovering, Inc.*, 05 CIV. 4485 (NRB), 2006 WL 250486 (S.D.N.Y. Feb. 2, 2006) (denying Rule 56 request for discovery where "[n]either counsel's declaration nor his memorandum of law suggests *how* the information he seeks will create a genuine issue of material fact, instead baldly asserting that it *may* do so." (emphasis in original)).

III. CONCLUSION

For the reasons outlined above, this Court grants Defendant's Motion for Summary Judgment [docket # 3152], and Denies the Gaynor Plaintiffs' Motion for Discovery [docket #3541]. An appropriate Order accompanies this Opinion.

Dated: June 17, 2014

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.