NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: FOSAMAX (ALENDRONATE SODIUM): PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** All Actions	**MDL No. 2243** Master Docket No. 08-08 (JAP)(LHG) **OPINION**

PISANO, District Judge

This matter is presently before the Court on an Order to Show Cause ("OTSC") issued on August 15, 2013 [docket #2895], directing the Plaintiffs listed in Appendix A of the Order (collectively referred to as "Plaintiffs"), to show cause why their pre-September 14, 2010, injury claims should not be dismissed on preemption grounds pursuant to this Court's ruling in the Bellwether *Glynn* case. *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).

In response to the OTSC, the Court received the following briefs from Plaintiffs: (1) Plaintiff Deborah Thompson's Response to the OTSC [docket #2931]; (2) Plaintiff Helen Stampliakas's Response to the OTSC [docket #2932]; (3) Plaintiff Elaine Howe's Response to the OTSC [docket #17 on 11-6657] (4) Plaintiffs' Adverse Reactions and Long-Term-Use Failure-to-Warn Brief ("Adverse Reactions Brief") [docket #2995(1)]; (5) Plaintiffs' Design-Defect and Other Non Failure to Warn Claims Brief ("Design Defect Brief") [docket #2995(2)]; (6) Plaintiffs' Procedural Brief [docket #2995(3)]; and (7) Plaintiffs' Warnings and Precautions Brief [docket #2995(4)].

Merck replied to Plaintiffs' response to the OTSC and filed the following briefs in support of its position: (1) Reply to Plaintiff Helen Stampliakas's and Plaintiff Deborah Thompson's Responses to the Court's OTSC [docket #3030]; (2) Reply to Plaintiff Elaine Howe's Response to the Court's OTSC [docket #3041] (3) Reply to Plaintiffs' Adverse Reactions and Long-Term-Use Failure-to-Warn Brief ("Merck's Adverse Reactions Brief") [docket #3031]; (4) Reply to Plaintiffs' Design Defect and Other Non-Failure to Warn Claims Brief ("Merck's Design Defect Brief") [docket #3031(1)]; (5) Reply to Plaintiffs' Procedural Brief [docket #3031(3)]; and (6) Reply to Plaintiffs' Warnings and Precautions Failure to Warn Brief [docket #3031(2)].

By way of brief background, Plaintiffs brought this lawsuit against 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 Plaintiffs' injuries, and Defendant failed to warn physicians about Fosamax causing AFFs. For the reasons set forth below, Plaintiffs' have failed to show cause why their pre-September 14, 2010, injury claims should not be dismissed on preemption grounds. Preemption was dispositive of *Glynn* and cuts across all pre-label change cases. Accordingly, Defendant is entitled to judgment as a matter of law on the Appendix A Plaintiffs' claims.

I. OVERALL PROCEDURAL HISTORY

In May 2011, the Judicial Panel on Multidistrict Litigation centralized in this Court a number of related actions brought by patients who suffered femur fractures or similar bone

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

injuries after taking Fosamax [docket #30]. On July 14, 2011, the Court ordered a process for selection of three or four Early Trial Cases and directed a schedule for expert discovery [docket #113]. On November 14, 2012, the Court designated trial dates for the four Early Trial Cases, with the earliest, *Glynn*, set for April 8, 2013 [docket #1915]. General fact discovery closed on December 31, 2012, pursuant to Case Management Order No. 10 [docket #848].

On January 15, 2013, Merck moved for summary judgment in *Glynn* on federal preemption grounds, arguing that the Plaintiffs' claims were preempted because the FDA's rejection of Merck's proposed Precaution disclosing a risk of low-energy femoral shaft fracture from Fosamax use made it impossible for Merck to warn the Plaintiffs' of that risk [docket # 25 in 11-5304]. This Court heard oral argument on the federal preemption issue on March 8, 2013, and reserved decision until a trial record had been established. A jury trial took place in *Glynn* from April 8, 2013 to April 29, 2013. The parties then briefed the preemption issue three more times: a Rule 50(a) motion for judgment as a matter of law at the close of Plaintiffs' case [docket # 198 in 11-5304]; a renewed Rule 50(a) motion at the close of all evidence [docket # 209 in 11-5304]; and a Rule 50(b) renewed motion for judgment as a matter of law [docket # 216 in 11-5304].

On June 27, 2013, after considering all of the parties briefing, evidence, arguments, and the trial record, the Court granted Merck's motion(s) and found that Plaintiff's state law claim for failure to warn was preempted because clear evidence existed that the FDA would not have approved a stronger warning to the Fosamax label as of the date of Ms. Glynn's injury. *Glynn*, 2013 WL 3270387, at *1. On August 1, 2013, Merck then moved for an OTSC why the claims of all other Plaintiffs with injury dates prior to September 14, 2010, should not be dismissed pursuant to the Court's preemption ruling in *Glynn* [docket #2857]. On August 5, 2013,

Plaintiffs' submitted a letter brief opposing the entry of an OTSC [docket #2870], and Merck replied by letter on August 12, 2013 [docket #2881]. The Court, observing that it had "afford[ed] the Plaintiffs' Steering Committee . . . and Glynn's counsel repeated opportunities to present their evidence" and that the *Glynn* ruling turned on issues common to all Plaintiffs, granted Merck's motion on August 15, 2013 [docket #2895].

As stated above, the parties submitted several briefs and filings in support of their responses to the OTSC. The Court will address each argument separately below.

II. BACKGROUND

A. History of the Fosamax Label Change

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. 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 [docket # 3032, *Merck's Preliminary Statement of Facts Relating to the Court's Order to Show Cause* ("Merck's Statement of Facts") ¶ 28]. 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.* at ¶ 44. 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.* at ¶ 43.

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

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. *Id.* at ¶ 47. The FDA's review of this data as well as the data from other bisphosphonate manufacturers "did not show an increase in . . . [the risk of atypical subtrochanteric femur fractures] in women using these medications." [docket #3035, *Declaration of Karen A Confoy in Support of Merck's Replies to Plaintiffs' Briefs in Response to Court's Order to Show Cause and in Support of Merck's Preliminary Statement of Facts* ("Confoy Dec."), Ex. 73].

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. Merck's Statement of Facts, ¶ 73. 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 is 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.
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> [*Id.* at ¶74].

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 April 15, 2009, an FDA representative e-mailed Defendant and stated that the label change to the Adverse Reactions/Post-Marketing Experience section of the label would be approved but the label change to the Precautions section would not be approved. *Id.* at ¶ 79. 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 still did not approve the label change to the Precautions section. *Id.* at ¶ 80. 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.*

On July 2, 2009, Defendant submitted to the FDA a Changes Being Effected ("CBE") supplement to add the FDA's proposed language about femur fractures to the Adverse Reactions/Post-Marketing Experience section of the label, which was later approved. *Id.* at ¶ 81. On March 10, 2010, the FDA issued a Drug Safety Communication, in which it stated that "[a]t this point, the data that FDA has reviewed have not shown a clear connection between

bisphosphonate use and a risk of atypical subtrochanteric femur fractures" *Merck's Statement of Facts*, ¶ 85. 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*. *Id.* at ¶ 86. The report stated that although there is an association between long-term bisphosphonate use and AFFs, the association had not been proven to be causal. *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." *Id.* at ¶ 87. 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 would be "*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." *Id.* at ¶¶ 88-89. It reiterated that it was still "not clear if bisphosphonates are the cause," but noted that these "unusual femur fractures" may be related to long-term bisphosphonate use. *Id.* at ¶ 88. The FDA's proposed labeling language noted that "[c]ausality

has not been established as these fractures also occur in osteoporotic patients who have not been treated with bisphosphonates." *Id.* at ¶ 89. On January 11, 2011, Defendant submitted the agreed upon label changes to the FDA. *Id.*

Currently, the Fosamax label includes the following language: "Atypical, low-energy, or low trauma fractures of the femoral shaft have been reported in bisphosphonate-treated patients. . . . 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." [docket #2996, *Declaration of Donald A. Ecklund* ("Ecklund Dec."), Ex. 9].

B. *Glynn* Ruling

As noted above, before the Court in *Glynn* were several motions by Defendant[3], all of which were premised on federal preemption. The issue in these motions was whether clear evidence existed that the FDA would not have approved a stronger warning to the Fosamax label, thereby warranting preemption of the *Glynn* Plaintiffs' failure to warn claim. *See Wyeth v. Levine*, 555 U.S. 555 (2009). This Court heard oral argument on the preemption issue on March 8, 2013, and reserved decision until a trial record had been established. *See* Fed. R. Civ. P. 78. A jury trial took place from April 8, 2013 to April 29, 2013, and the jury returned a verdict for Defendant, finding that Plaintiff Glynn did not prove that she experienced an AFF in April 2009 by a preponderance of the evidence.

On the day following the conclusion of the trial, the Court held an in-person status conference where it discussed the preemption issue and gave the Plaintiffs twenty-one (21) days

[3] The motions before the Court in *Glynn* were: (1) Defendant's Motion for Summary Judgment based upon Federal Preemption [docket # 25 in 11-5304]; (2) Defendant's Motion for Judgment as a Matter of Law pursuant to Rule 50(a) [docket # 198 in 11-5304]; (3) Defendant's Renewed Motion for Judgment as a Matter of Law pursuant to Rule 50(a) [docket # 209 in 11-5304]; and (4) Defendant's Renewed Motion for Judgment as a Matter of Law pursuant to Rule 50(b) [docket # 216 in 11-5304].

to submit "proposed fact findings that [were] based upon the record in opposition to" the preemption motions. [docket #250 in 11-5304, *Hearing Tr.*, 19:24-20:1; April 30, 2013]. Thereafter, on May 6, 2013, Defendant submitted its Renewed Motion for Judgment as a Matter of Law pursuant to Rule 50(b) [docket # 216 in 11-5304], arguing that the *Glynn* Plaintiffs' claims were preempted because Defendant submitted to the FDA all of the information relevant to a label change and tried to change the Precautions section of the label to include low-energy femoral fractures, but the FDA rejected this change. The Court agreed with Merck's position and on June 27, 2013, granted Defendant's motion(s). See Generally *Glynn*, 2013 WL 3270387.

C. Arriving at the OTSC

With the history of *Glynn* as a backdrop, it is necessary to address the evolution of the preemption issue, how the case has gotten to the point of having an OTSC on the issue, and the fact that the parties have been aware of the potential global effects preemption could have on the entire MDL for at least two (2) years. Throughout the entire pre-trial, trial, and post-trial proceedings in *Glynn*, the Court made it clear that, prior to ruling on preemption, it wanted the parties to introduce *any and all relevant evidence* to the issue because of the effects it could have on the MDL as a whole. During this time – even prior to any motions being filed by Defendant – Plaintiffs' were aware of the exact position that Merck took surrounding preemption, how Merck planned to raise this argument, and the fact that Merck believed preemption likely hinged on the date of a Plaintiff's injury.

Indeed, before Ms. Glynn was even selected as the Bellwether case for trial, the parties appeared before the Court on May 14, 2012, where counsel for Merck reiterated the fact that the date of injury was central to the analysis and advised the Court and Plaintiffs of Defendant's position on preemption. [docket #1397, *Hearing Tr.*, 13:25-14:2; 14:12-14:14; 15:16-15:19;

22:5-22:7; May 14, 2012 ("MR. MARSHALL: . . . I want to focus in on some of the labeling issues because they're going to be very important in the case . . . [it's] going to be a very important point in these cases because we will be raising a preemption argument . . . [t]hat defense will be raised as a substantive legal motion . . . [and] it will be based upon when the injury occurred . . . [a] key factor . . . is the timing of the injury. . . .")]. Stated differently, for almost an entire year prior to the *Glynn* trial, Plaintiffs were aware of Defendant's position on preemption, the fact that it would be raised by way of substantive motion and that such motion would be directly related to the timing of injury. Fact discovery closed seven (7) months thereafter and the preemption issue was then briefed four separate times.

As the *Glynn* trial moved closer, the parties were advised of the Court's desire to have any and all arguments and evidence relevant to preemption on the record. [docket #244 in 11-5304, *Trial Tr., Vol. 9*, 1885:7–1885:12; April 22, 2013 ("THE COURT:. . . I have indicated my intention to ultimately rule on that [preemption] motion after I've had the benefit of a complete trial record . . . I think I'm correct that a full trial record would benefit me and both sides before a ruling is made.")]. Further, after the close of Plaintiff's case in the *Glynn* trial, Plaintiffs were *again* made aware of the exact position Merck took with respect to the evidence set forth and the issues Merck planned to *again* raise surrounding preemption. *Id.* at 1908:12 – 1908:17 ("MR. MARSHALL: . . . The FDA had in its possession all of the information that plaintiffs now rely upon to say that a label change could be made. We tried to do it, it was rejected. We are precluded, prevented from doing it. That, your Honor, is the preemption argument."). Despite Merck's contention that no dispute of fact existed for the jury to decide, the Court continued to reserve its decision on the preemption motion(s) to ensure a full trial record was established with *all evidence* relevant to the issue.

Immediately following the trial on April 30, 2013, the parties appeared before the Court to discuss the process of moving the MDL forward and, again, the Court reiterated that it has been urging Plaintiffs to come forward with *any and all evidence* on the preemption issue, as the parties all agreed that it would have widespread implications on the MDL as a whole:

> MR SEEGER: . . . **I'm thinking that the preemption issue because it's going to cut across all 3,000 cases. Pretty much if it goes the wrong way for plaintiffs, it's pretty much the end of the litigation.**
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> . . .
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> THE COURT: There have been three iterations of the preemption motion and **my position all along was to make – that I wanted to be sure, first of all, that I had a complete record from which to decide the preemption issue.** And I thought the best way to do that was to try the Glynn case, because that was the case that was coming in, knowing that there was going to be **evidence introduced which would bear upon Merck's conduct with the FDA and whether there would be clear evidence that [the] FDA would not have permitted the label change**, which is what Merck has to show under *Wyeth v. Levine*.
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> . . .
>
> I don't know what more you want to put in the record. **I invited you, I invited the plaintiffs and I was urging the plaintiffs to put in what there could be bearing on the question.** I don't know what else there is.
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> . . .
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> **The issue in the case is whether there's anything in the regulatory record from which the Court would conclude that it's clear the FDA would not have permitted the label change.** Now, the label change was an issue in the Glynn case. It was an issue in the Glynn case that was addressed by Dr. Blume, it was addressed by Dr. Madigan and it certainly was addressed by Dr. Santora and Daifotis.
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> **I'm not so sure there's anything else and if there was something else, I have been begging for it.**
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> . . .
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> . . . **It was clear to me and everybody else that there was substantial consequences to this motion. We've had a hundred conversations, all of us, since then where I have been saying the same thing, namely, that I wanted -- that it was important to decide this case, this issue one way or another so that there could be some appellate review and we get a sense of it, because we know we're holding 3300 cases hostage.**

[docket #250 in 11-5304, *Hearing Tr.*, 5:10-5:13; 6:10-6:19; 7:13-7:17; 16:6-16:14; 18:15-18:21; April 30, 2013 (emphasis supplied)].

Similarly, after the Court granted Merck's preemption motion(s) in *Glynn*, the parties appeared before the Court on July 18, 2013, to again address, among other things, how the preemption issue would be treated going forward and the fact that preemption would cut across all of the cases in the MDL:

> THE COURT: I think it's an accurate statement, Mr. Morris, that **I have been consistent in asking the plaintiffs to come forward with any evidence that would bear upon that preemption decision and I didn't decide it until I was satisfied that there had been a full opportunity to be heard on the question and the opinion stands for itself.**
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> . . .
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> This business about all the plaintiffs having their own claims and their own injuries and their own doctors is all very well and fine and that's true, **but the focus from the preemption issue, the focus is more on Merck than on the plaintiffs**.
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> . . .
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> THE COURT: . . . [W]hat I would expect then is there to be some sort of an effort by Merck to close the door on these cases.
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> MR. MORRIS: **Right, we expected that**. . .

[docket #2998, *Hearing Tr.*, 10:3-10:8; 10:16-10:20; 11:8-11:10; July 18, 2013 (emphasis supplied)].

As a review of the record reveals, the preemption issue has existed since this MDL's inception and preemption has almost certainly been the forefront of the litigation for the past two (2) years. It has never been a secret as to what Merck's position is with respect to preemption, and Plaintiffs have long been aware that their case(s) may depend entirely on the date of injury. Further, as referenced above, for the past two (2) years the parties and the Court have been operating under the common understanding that this Court's decision on preemption could impact the entire MDL. Stated differently, Plaintiffs and Defendant knew that while the motions

before the Court in *Glynn* were specific to the date of Ms. Glynn's injury, the Court's decision on such motions would almost certainly have an effect on a substantial amount of Plaintiffs other than Ms. Glynn. Thus, the Court purposely reserved deciding the issue to ensure that *any and all facts relevant to preemption* would appear on the record. In doing so, the Court repeatedly urged Plaintiffs to come forward with all evidence bearing on preemption, allowed the parties several opportunities to brief the issue, entertained oral argument on the motion(s), conducted an entire trial which invited any evidence relevant to preemption, and addressed the issue at various hearings. Then, after finally ruling on preemption in *Glynn*, the Court issued an OTSC – giving the parties yet another opportunity to brief the issue – to address what has *long* been known as a predominant issue in the case: namely, what effect does the Court's preemption ruling have on the other Plaintiffs whose injuries occurred prior to the date of the label change?

III. DISCUSSION

A. Procedural Arguments

The parties each submitted briefing on the procedural aspects of the Court's OTSC in the context of an MDL. Plaintiffs' and Defendant concede that Rule 56 provides the proper standard for the Court's analysis here; however, the parties disagree over the burden shifting, as well as the Court's ability to utilize an OTSC to apply the *Glynn* ruling to other Plaintiffs. This Court agrees with the parties' contention that Rule 56 provides the exclusive mechanism by which the Court can resolve the dispositive issues presented by Merck's preemption defense before trial(s).

i. Procedural Analysis

The Court must first address the proper standard to be applied pursuant to Rule 56 as well as where the appropriate burden lies in this OTSC context. Under Rule 56, summary judgment is applicable when the Court is satisfied that there is no genuine issue of material fact and the

evidence establishes the moving party's entitlement to judgment as a matter of law. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553 (1986). "If the moving party meets the initial burden of establishing that there is no genuine issue, the burden shifts to the nonmoving party to produce evidence of a genuine issue for trial." *Degrange v. W.*, 196 F. App'x 91, 93 (3d Cir. 2006).

This Court agrees with Merck's contention that Defendant's initial burden pursuant to Rule 56 has already been met by way of the briefing in *Glynn*. As stated above, Merck briefed the preemption issue four (4) separate times and in doing so, met its burden of establishing that there is no genuine issue(s) of fact with respect to preemption. This is further evidenced by the Court's judgment as a matter of law in favor of Merck, holding that clear evidence exists that the FDA would not have approved a stronger warning prior to the date of Ms. Glynn's injury.[4] See Generally *Glynn*, 2013 WL 3270387. Thus, Merck has demonstrated the absence of any genuine issue of material fact surrounding preemption and the burden is therefore shifted to Plaintiffs to produce a genuine issue for trial by way of their briefing in response to the Court's OTSC.

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[4] It should be noted, however, that despite the *Glynn* ruling being specific to Ms. Glynn and the date of her injury, Merck's briefing in *Glynn* is still relevant to all Plaintiffs' identified in this Court's OTSC because the briefs in *Glynn* centered generally on when clear evidence existed that the FDA would not have approved a label change. See *Defendant Merck Sharp & Dohme Corp.'s Memorandum of Law in Support of Motion for Summary Judgment Based upon Federal Preemption*, p. 18 [docket #25 in 11-5304] (". . . [I]t was not until the ASBMR report was issued in September 2010, reporting that bisphosphonates, when used long-term, may be related to femoral fractures, that the FDA determined available scientific evidence supported a Precaution."); *Defendant Merck Sharp & Dohme Corp.'s Memorandum of Law in Support of its Motion for Judgment as a Matter of Law*, p. 2, 18 [docket #198 in 11-5304] and *Defendant Merck Sharp & Dohme Corp.'s Memorandum of Law in Support of its Renewed Motion for Judgment as a Matter of Law*, p. 1, 12 [docket #209 in 11-5304] ("[Plaintiff's] claims would be preempted because Merck proposed . . . such a Precaution and the FDA rejected it . . . such a rejection is "clear evidence" that the FDA would have rejected any warning about fractures . . ." and "Dr. Blume testified clearly and repeatedly . . . that a pharmaceutical company's duty to change its label to warn of an adverse event does not arise until there is 'reasonable evidence of a causal association' under 21 C.F.R. § 201.57"); *Merck Sharp & Dohme Corp.'s Reply in Support of Rule 50(B) Motion for Judgment as a Matter of Law*, pp. 5-6 [docket #230 in 11-5304] ("Simply put: the change in the FDA's approach between 2008 and 2010 did not result from a change in FDA policy with respect to line-editing proposed warnings . . . Rather, it resulted from an evolution in the FDA's views about the science relating to atypical femur fractures, which did not crystallize until late 2010.").

Plaintiffs' assert that they have met this burden because subsequent to the *Glynn* ruling, there have been additional documents exchanged and additional expert testimony which creates a genuine issue of fact as to what Merck could have or should have done in connection with updating its label.[5] However, what Merck *could have* or *should have* done is immaterial because we know what Merck *did*. Similarly, *Wyeth v. Levine* provides for preemption where there is clear evidence that the FDA *would have* rejected a label change, and again, we know that the FDA *did* reject it. Thus, any expert testimony relating to what Merck *could have* or *should have* done, and what the FDA *would have* done in response to the same, is purely speculation and does not rise to the level of being a genuine fact dispute. Allowing Plaintiffs the opportunity to present individual expert testimony would also defeat the efficiency of an MDL because Plaintiffs would go through expert after expert, and none of the testimony would change what actually transpired between Merck and the FDA.

Further, the Court disagrees with Plaintiffs' contention that their Seventh Amendment rights and the procedural protections safeguarded in Rule 56 are being circumvented. Plaintiffs' suggest that the preemption determination must be made by a fact finder; however, if this were the case, the Court's preemption ruling in *Glynn* would be improper.[6] This assertion is not convincing. Rather, as evidenced by the cases cited to by Plaintiffs, where there is *no factual dispute* surrounding a preemption determination, summary judgment is proper. See *Boyle v. United Technologies Corp.*, 487 U.S. 500, 501, 108 S. Ct. 2510, 2513 (1988) ("If the evidence

[5] Plaintiffs' claim that "new evidence" presently before the Court includes Ex. 161 to the *Declaration of Donald A. Ecklund*, which was a statement from the FDA in December, 2010 about why it was rejecting the label change and that because the FDA struck out the term "stress fracture," this Court cannot find that clear evidence exists that the FDA would have rejected a label change that did not use the "stress fracture" language. However, it should be noted that the December, 2010 statement from the FDA was before the Court in *Glynn* and therefore, this is not "new evidence" that the Court has not already considered in determining that no material fact dispute exists. See *Declaration of Edward Braniff in Support of Plaintiff's Opposition to Defendant's Motion for Judgment as a Matter of Law*, at Ex. 1 [docket #199 to 11-5304].

[6] It should be noted that Plaintiff Glynn did not appeal this Court's June 27, 2013, Order on preemption.

presented in the first trial would not suffice, as a matter of law, to support a jury verdict under the properly formulated [preemption] defense, *judgment could properly be entered for respondent at once*, without a new trial. It is unclear from the Court[s] of Appeals' opinion, however, whether it was in fact *deciding that no reasonable jury could*, under the properly formulated [preemption] defense, have found the petitioner on the facts presented, or rather was assessing on its own whether the defense had been established. *The latter would be error*, since whether the facts established the conditions for the [preemption] defense is a question for the jury." (emphasis supplied)); *Brown v. Earthboard Sports USA, Inc.*, 481 F.3d 901, 913 (6th Cir. 2007) ("*Should the movants fail to meet their burden* . . . such as *if a genuine issue of material fact exists* regarding the claim's actual qualification for federal preemption, the matter must be determined by the factfinder." (emphasis supplied)).

Plaintiffs' procedural protections and Seventh Amendment argument is no more than a reiteration of the summary judgment standard. As the Court has already stated, Merck met its burden of proving that no there is no genuine issue of fact surrounding preemption by way of the briefing and trial record developed in *Glynn*. As a result, Plaintiffs are being afforded the procedural protections of Rule 56, and this Court is neither violating their Seventh Amendment rights nor "deciding factual disputes." Were the Court to determine that there *is* a genuine dispute of fact, it would deny summary judgment; however, in determining that there *is no factual dispute*, the Court is not thereby "deciding factual disputes."

Moreover, utilizing an OTSC to apply a prior legal ruling to other Plaintiffs in an MDL is hardly inappropriate as suggested by Plaintiffs. Rather, several MDL courts have used an OTSC to do just that. See *In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, 2012 WL 3290145, at *1 and fn. 1 (E.D. Ky. Aug. 10, 2012)("Here, the Court has previously determined

that product liability claims against Generic Defendants are preempted . . . [The Show Cause Order] directed all plaintiffs with claims against any Generic Defendant to show cause why those claims should not be dismissed pursuant to the Court's Memorandum Opinion and Order Regarding Generic Defendants' Motions to Dismiss."); *In re Allstate Ins. Co. Fair Labor Standards Act Litig.*, 2009 WL 3011042, at *1 (D. Ariz. Sept. 16, 2009)("[I]n this MDL action . . . summary judgment would be granted in the defendants' favor as to all claims of any Continuing Plaintiff who did not show cause in writing . . . explaining why the Court's reasoning in the summary judgment order . . . which the Court entered in the . . . member case, should not be applied to him or her."); *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig.*, 455 F. Supp. 2d 709, 712-13 (N.D. Ohio 2006)("In *Moore*, Sulzer moved for summary judgment on the ground that all of Moore's claims were preempted by federal law . . . In light of the Court's conclusion in *Moore*, Sulzer moved the Court to issue an Order requiring all similarly-situated plaintiffs . . . to show cause why their cases should not also be dismissed. The Court acquiesced to this request."). In doing so, the Court is not applying a *factual* determination made in *Glynn* to the Plaintiffs identified in the OTSC, but a *legal* determination: namely, that there is clear evidence the FDA would have rejected a stronger Fosamax warning label, thereby preempting Plaintiffs' claims.

Further, the OTSC does not give an impermissible preclusive effect to the *Glynn* ruling because the Court is not automatically applying the holding in *Glynn* to other Plaintiffs. Instead, despite having been aware of the preemption issue for two (2) years, briefing the issue four (4) separate times, and conducting an entire trial whereby any evidence relevant to preemption could be introduced, the OTSC provides affected Plaintiffs *another* opportunity to identify genuine issues of material fact that would preclude summary judgment on their claims. Plaintiffs' failure

to meet their burden pursuant to Rule 56 does not then equate to issue and/or claim preclusion. Plaintiffs' contention that further factual and expert discovery should be afforded these Plaintiffs, and that each MDL Plaintiff is entitled to litigate the preemption issue, is similarly misguided. The Court has repeatedly advised Plaintiffs' counsel to come forward with any and all evidence surrounding preemption; thus, the failure to properly gather factual and expert discovery prior to this OTSC is no fault other than Plaintiffs. Additionally, in making these discovery related arguments, Plaintiffs are improperly focusing on the relationship between the *individual Plaintiffs* and *Merck*; however, as the Court has explicitly stated on the record, the preemption analysis is entirely dependent on the relationship between *Merck* and the *FDA*.

The Court is not convinced that, whether clear evidence exists that the FDA would have rejected a stronger warning label to Fosamax, has any relevance to the individual Plaintiff and his or her potential factual differences. Rather, the material fact relevant to the preemption determination and the OTSC does not differ amongst the Plaintiffs listed in Appendix A – an injury that occurred prior to September 14, 2010. Plaintiffs have failed to show how uncovering additional information on behalf of each individual Plaintiff would change the analysis or preclude summary judgment here and therefore an extension of discovery is not warranted. See *Penn. Dep't of Pub. Welfare v. Sebelius*, 674 F.3d 139, 157 (3d Cir. 2012). Further, while the Court is sympathetic to the Plaintiffs and their respective injuries, to give each of the Plaintiffs identified in the Courts OTSC their "own day in court" to litigate a legal issue that has already been conclusively determined would not only be a waste of judicial resources but would be contradictory to the premise of pre-trial motions and summary judgment. While Ms. Glynn had her "day in court," such was for the purpose of developing a complete trial record on the

preemption issue; however, the Court need not have several hundred trial records, with the same evidence, to decide the very same issue.

As Merck correctly points out, this case is distinguishable from *In re TMI Litig.*, 193 F.3d 613 (3d Cir. 1999) *amended*, 199 F.3d 158 (3d Cir. 2000) because there, the Third Circuit concluded that the District Court "could not properly extinguish the substantive rights of the 1,900 Non-Trial Plaintiffs *merely because* all of the cases had been consolidated . . . because the Non-Trial Plaintiffs were not even litigating their claims and not presenting arguments to the District Court." *Id.* at 725 (emphasis supplied). Here, the Court is not merely applying its ruling in *Glynn* to Plaintiffs, but has repeatedly urged Plaintiffs to come forward with evidence as to why their claims are not preempted, is giving Plaintiffs another opportunity in the context of the OTSC to present arguments to the Court as to why their claims are not preempted, and is applying the Rule 56 standard in doing so.

The Court has consistently made clear that it expected Plaintiffs to present all of the pertinent evidence on the issue of preemption by the end of the *Glynn* trial. Thus, Plaintiffs' argument that they have been denied the opportunity to develop expert testimony relevant to the preemption issue is ill-advised. The Court is also satisfied that additional individualized factual discovery is unnecessary because the crux of the preemption inquiry focuses on the relationship between Merck and the FDA, and has nothing to do with the facts or injuries of the individual Plaintiffs.[7] Stated differently, facts relating to *each individual Plaintiff* will not have any effect on whether *Merck* had a duty to warn, and testimony from individual experts regarding what Merck and the FDA *could* or *would* have done will not change what Merck and the FDA *did*. Accordingly, the Court finds that utilizing an OTSC to apply the *Glynn* ruling to those Plaintiffs'

[7] Individualized discovery may be appropriate if the parties were disputing *causation* such as the Plaintiffs in *TMI*; however, the preemption analysis here is dependent on whether *Merck* had a state law *duty* to update its warning label.

whose injuries occurred prior to September 14, 2010, without allowing additional discovery is not improper.

B. Design Defect and Other Non-Failure to Warn Claim Arguments

The parties each submitted briefing with respect to whether the Court should utilize the OTSC to apply the *Glynn* preemption ruling to Plaintiffs' design defect and other non-failure to warn claims. In support of their position, Plaintiffs' argue that the Court's preemption ruling in *Glynn* only applied to a state law failure to warn claim and therefore did not address, and cannot be applied to, state law claims for design defect, negligence, fraud, breach of warranties, consumer protection/deceptive trade practices, and unjust enrichment. Specifically, Plaintiffs' argue that these claims do not "emanate from a general theory that Merck failed to provide an adequate warning about the risk of atypical femur fractures" and therefore, Defendant has not met its Rule 56 burden to obtain summary judgment on these claims. See *Plaintiffs' Design Defect Brief*, at p. 8.

i. Design Defect and Other Non-Failure to Warn Claim Analysis

As discussed in the procedural analysis, Merck's Rule 56 burden surrounding preemption was met by way of the briefing in *Glynn*. Plaintiffs' contention that applying the *Glynn* ruling to design defect and other non-failure to warn claims would improperly relieve Merck of its burden to show that it is entitled to judgment on such claims is, in the abstract, persuasive. Importantly, however, Plaintiffs' design defect and other non-failure to warn claims are based entirely on the premise that Fosamax had risks which should have been disclosed to consumers. Thus, these claims rise and fall with a claim for failure to warn and utilizing an OTSC to preempt Plaintiffs' design defect and other non-failure to warn claims based on this Court's ruling in *Glynn* is not improper. See *Cooper v. Bristol-Myers Squibb Co.*, 2013 WL 85291, at *9 (D.N.J. Jan. 7,

2013)("Therefore, having already determined that Plaintiff is unable to establish any triable issue with respect to his failure-to-warn claim, Plaintiff's design claim correspondingly fails."); *Begley v. Bristol-Myers Squibb Co.*, 2013 WL 144177, at *9 (D.N.J. Jan. 11, 2013)(". . . [A] product bearing an adequate warning is not in [a] defective condition, nor is it unreasonably dangerous . . . Hence, Plaintiff's defective design claim fails because she has not demonstrated that the [product's] warning was inadequate." (internal citations omitted)); *Stafford v. Wyeth*, 411 F. Supp. 2d 1318, 1320 (W.D. Okla. 2006)(granting summary judgment to Defendant where plaintiff failed to establish that Defendant's failure to warn was the proximate cause of her injury and plaintiff's non-failure to warn claims, including negligence and design defect, "all hinge on defendant's alleged failure to warn."); *Chatman v. Pfizer, Inc.*, 2013 WL 1305506, at *4 (S.D. Miss. Mar. 28, 2013) (". . . [T]he national consensus is that [plaintiff's] other claims are poorly camouflaged failure-to-warn claims, and therefore most courts have rebuffed plaintiffs' attempts to recover under alternative state-law theories of liability including negligence and fraud. . . If [plaintiff's] remaining claims are disguised failure-to-warn claims, then they are unquestionably subject to [the failure to warn] preemption analysis" . . . Further, "[t]here can be no doubt that [plaintiff's design defect] claims are [also] based on the inadequacy of the warning she was given, and therefore these claims are subject to [preemption] . . ." (internal citation omitted)).

Plaintiffs' contend that neither their negligent design defect nor strict liability design defect claims sound in failure to warn, but that fact questions exist as to whether Fosamax was unreasonably dangerous, or whether Merck was negligent in failing to conduct adequate testing and use due care in the design and manufacture of Fosamax. In support of this argument, however, Plaintiffs' advance only a summary of the law and tests that may be applied to determine if a product is defectively designed but offer no law as to which test applies here and

no facts and/or evidence to show that Fosamax was in fact defectively designed or that Merck acted negligently. Further, aside from the pleadings, this appears to be the first time in a six (6) year-long litigation, after a two (2) year focus on preemption, discovery, numerous briefs on the preemption issue and an entire trial worth of evidence, that Plaintiffs' believe Fosamax was defectively designed or that Merck was negligent in conducting testing of the drug. The entire MDL has centered on Merck's conduct in failing to update Fosamax's warning label.

To this end, Plaintiffs' make a conclusory statement that their complaints have "typically alleged" facts in support of their non-failure to warn, strict liability and negligence based design defect claims, but offer no facts as to which, or how many Plaintiffs have in fact pled such claims. Plaintiffs' are conflating the standard to withstand a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss with the standard to be applied here, which is that of a Rule 56 motion for summary judgment. Surely, Plaintiffs general description of what some complaints "typically allege" may constitute plain statements showing that Plaintiffs are entitled to relief, see *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557, 127 S.Ct. 1955 (2007); however, meeting the threshold requirement of Rule 12(b)(6) is hardly sufficient to defeat Merck's showing that it is entitled to judgment as a matter of law on preemption grounds.

Indeed, Merck has met this burden. Plaintiffs' design defect and other non-failure to warn claims are merely disguised failure to warn causes of action, which is evidenced by the pleadings that Plaintiffs attach as exhibits in response to the OTSC and the fact that the entire litigation, focus of the parties' discovery, and evidence put before the Court has been based entirely on Fosamax's warning. In fact, one of the complaints cited to by Plaintiffs in support of the argument that the design defect claims are independent of the warning specifically states that "Fosamax, as researched, tested, developed, designed, licensed, manufactured, packaged,

labeled, distributed, sold and marketed by Defendant *was defective due to inadequate warnings and instructions*." See [docket #2996, *Ecklund Dec.*, Ex. 167 at ¶ 97 (emphasis supplied)]. Plaintiffs have not alleged that Fosamax's chemical composition could have been changed, but rather, that the product was unreasonably dangerous because it was not accompanied by a proper warning. Similarly, Plaintiffs' negligent design defect claims allege that Merck failed to properly test the drug, and had Merck exercised due care in testing the product, Fosamax's label would have been updated sooner. Again, however, these contentions are nothing more than speculation and while Plaintiffs' design defect and other non-failure to warn arguments begin by focusing on the product and/or Merck's conduct on the front end, they conclude by focusing on how the consequence – the label – *may* have been different as a result. See *Estate of Popolizio v. Ford Motor Co.*, 2013 U.S. Dist. LEXIS 79361, at *5-6 (D.N.J. June 5, 2013)("the non-moving party cannot rely on unsupported assertions, bare allegations, or speculation to defeat summary judgment.").

The Court also disagrees with Plaintiffs' contention that state law design defect claims cannot be preempted under the federal Food, Drug, and Cosmetic Act ("FDCA"). Plaintiffs make this assertion by stating that every Federal Circuit Court to address whether the FDCA preempts design defect claims has found no preemption; however, instead of providing the Court with an analysis of how, or if, the cases are even applicable to the facts here, Plaintiffs merely list the case names and citations. As Merck correctly points out, the cases cited to by Plaintiffs are distinguishable from the instant matter and therefore, carry little weight with respect to whether Plaintiffs' design defect claims can be preempted.[8]

[8] In *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), the Second Circuit held that because Plaintiff's state law causes of action merely required *some* proof of fraud on the FDA but such proof was not conclusive, the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 121 S. Ct. 1012 (2001) that all fraud on the FDA claims are preempted did not apply to *automatically* preempt Plaintiff's state law claims which

Accordingly, because Plaintiffs' design defect and other non-failure to warn claims are entirely based, and ultimately hinge, on the adequacy of Fosamax's warning, these claims are preempted and must fail as a matter of law. Regardless of what state law applies to each Plaintiff's individual design defect and other non-failure to warn claims, Merck simply cannot be liable for not having a warning on its product that was rejected by the FDA as of the date of a Plaintiff's injury. Because the Court has already found that pursuant to *Wyeth v. Levine*, clear evidence exists that the FDA would have rejected a stronger warning label, and the crux of Plaintiffs' design defect and non-failure to warn claims is the adequacy of the warning, Defendant is entitled to summary judgment on these claims.

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only incidentally involved fraud. The Court in *Desiano* did note that state based tort liability falls within a state legislature's prerogative to regulate matters of health and safety and therefore, a presumption against preemption should apply; however, the Court went on to state that "there may be reasons to override that presumption [against preemption]." See *Desiano*, 467 F.3d at 94. Here, however, the Court is not applying preemption based on a fraud on the FDA theory to *automatically* preempt Plaintiffs' remaining claims that *incidentally* relate to fraud but rather, after giving Plaintiffs' an opportunity to be heard, is applying preemption based on a failure to warn ruling to preempt Plaintiffs' remaining claims that are based entirely on this same theory.

Abbot by Abbot v. Am. Cyanamid Co., 844 F.2d 1108 (4th Cir. 1988) is similarly distinguishable to the instant matter because there, the Court was faced with a preemption analysis specific to vaccines. Notably, as the *Abbot* Court pointed out, Congress expressly dealt with vaccines in 1986 and 1987 and did not preempt state law; thus, the legislative intent surrounding vaccines weighed against preemption. Further, the Court's holding ultimately stands for the proposition that preemption is not *automatic*, as the Court stated that "[p]reemption does not follow *immediately* from the comprehensive federal regulation of prescription biological products. Every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute [automatically] ousts all related state law." *Id.* at 1112 (emphasis supplied)(internal citation omitted). The other cases cited to by Plaintiffs' reach a similar conclusion when dealing with vaccines. See *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1988)(". . . we believe that any case for preemption is doomed by the National Childhood Vaccine Injury ["NCVI"] Act of 1986."); *Graham by Graham v. Wyeth Labs., Div. of Am. Home Products Corp.*, 906 F.2d 1399, 1405 (10th Cir. 1990)(indicating that federal preemption does not *automatically* apply to bar plaintiff's state tort law claims relating to an improperly manufactured vaccine just because such vaccine met the FDA's minimum standards. (emphasis supplied)).

Similarly *Wimbush v. Wyeth*, 619 F.3d 632 (6th Cir. 2010) dealt with whether state law claims relating to negligence by a defendant that occurred prior to FDA approval are preempted by the FDA's subsequent approval of the drug. There, the Court specifically stated that it "hold[s] *merely* that FDA approval does not *automatically* preempt state law tort claims for negligence." *Id.* at 646 (emphasis supplied). Further, the Court notes that, of all the cases cited to by Plaintiffs' in support of their argument that design defect claims are not preempted by the FDCA, *Wimbush* is the only case that was decided after *Wyeth v. Levine*, 555 U.S. 555 (2009), and notably, *Wimbush* has the most narrow holding with respect to preemption.

C. Adverse Reaction and Long-Term-Use Failure to Warn Arguments

Plaintiffs argue that their failure to warn claims cannot be preempted because *Glynn* was specific to Merck's failure to update the Precautions section of the Fosamax label, but that Merck has not met its burden to show clear evidence exists that the FDA would have rejected a change to the Adverse Reactions section of the label or a change relating to the long-term use/shifting risk-benefit profile of Fosamax. While Plaintiffs acknowledge that Merck did in fact update the Adverse Reactions section of the Fosamax label in June 2009, Plaintiffs argue that a genuine dispute of fact exists as to whether Merck could have updated the Adverse Reactions section of the label *before* that time.

i. Adverse Reaction and Long-Term Use Analysis

There are several issues surrounding Plaintiffs' arguments. First, as stated above, Merck updated the Adverse Reactions section of its label in June, 2009. The OTSC has instructed Plaintiffs' with injuries occurring prior to September 14, 2010, to show cause why their claims should not be preempted. Upon review of the Plaintiffs' listed in Appendix A of the OTSC, nearly half of them have injuries which occurred between June, 2009 and September 14, 2010. Thus, to state that Plaintiffs' failure to warn claims are not preempted because they are based on the Adverse Reactions section of the label and not the Precautions section is illogical. Rather, almost half of the Plaintiffs identified in the OTSC were injured when there was *already* an Adverse Reactions warning on the label[9]; therefore, the only plausible failure to warn claims available to such Plaintiffs would have to be based on the Precautions section.

Second, to the extent that Plaintiffs' injuries occurred prior to the June, 2009 Adverse Reactions label change, Plaintiffs assert that there is evidence showing that a fact question exists with regard to whether Merck should have updated this section of the label sooner. As an initial

[9] Plaintiffs do not dispute the adequacy of the Adverse Reactions label.

matter, Plaintiffs do not plead this theory of liability in any of their complaints, nor have Plaintiffs set forth evidence indicating that any doctor would not have prescribed Fosamax if the occurrence of low-energy femoral shaft fractures had been mentioned in the Adverse Reactions section prior to 2009. Further, Plaintiffs' argument is one that was already made – also at the last hour – in *Glynn* and, prior to trial, Plaintiffs asserted that the evidence would show that Merck should have acted sooner to report the information it was receiving about fractures to the FDA. *Hearing Tr.*, 71:20-22; 72:8-10, March 8, 2013 ("MR. HONNOLD: The argument is, is the data was clearly there and **the evidence will be** Merck did not act upon it. . . it could have and should have been done differently based upon the information that Merck had in its possession and sat on and did nothing with.")(emphasis supplied); see also *Plaintiff's Preemption Supplement in Opposition to Defendant's Motion for Summary Judgment Based Upon Federal Preemption, Rule 50(a), and Rule 50(b) Motions* [docket #218 at 11-5304] ("[T]here is considerable evidence demonstrating that Merck should have at a minimum updated the [A]dverse [R]eactions section of its label as early as 1999.").

This argument is again dependent on the communication of information between *Merck* and the *FDA*, and is of no consequence to the individual Plaintiff. Plaintiffs presented evidence on this issue during the *Glynn* trial and argued that such evidence proves that Merck should have acted sooner; however, this Court was not convinced. The argument being presented by Plaintiffs now is no different than that which was already considered in *Glynn* because the evidence relevant to this claim is what *Merck* submitted to the *FDA* and such communications are the exact same regardless of which Plaintiff is before the Court. Thus, as in *Glynn*, the Court is still not convinced and Plaintiffs cannot recharacterize their failure to warn claims at this stage of the litigation as one involving the Adverse Reactions section of the label in order to overcome

the preemption issue. See *In re Fosamax Prods. Liab. Litig. (Boles v. Merck & Co.)*, 2010 WL 1257299, at *5 (S.D.N.Y. Mar. 26, 2010) ("[Plaintiff] cannot recharacterize her claim during trial in an effort to overcome the lack of evidence…").

Third, Plaintiffs' risk-benefit argument surrounding the efficacy of Fosamax was also already considered in *Glynn*. The Court did not accept Plaintiffs' efficacy argument in *Glynn* for the same reason it will not accept this argument here: the omission of efficacy information does not constitute a failure to warn about a drug's risks and therefore, does not raise a genuine issue of material fact as to whether Plaintiffs' failure to warn claims are preempted. See *LaBarre v. Bristol-Myers Squibb Co.*, 2013 WL 6053840, at *4 (3d Cir. Nov. 18, 2013)("In short, [the drug's] efficacy is irrelevant to [Plaintiff's] failure to warn claim, and the physicians' purported lack of information about it is of no consequence to the adequacy of the warnings.").

In sum, Plaintiffs' contention that the Adverse Reaction section of the label should have been updated prior to 2009, or that efficacy information should have been communicated on the Fosamax label, do not fall outside the scope of *Glynn* and the OTSC nor do they raise genuine issues of material fact with regard to whether clear evidence exists that the FDA would have rejected a label change. Accordingly, Plaintiffs' failure to warn claim(s) are preempted.

D. Warnings and Precautions Failure to Warn Arguments

Plaintiffs argue that their failure to warn claims are not preempted because communications from the FDA reflect that clear evidence does not exist as to whether the FDA would have rejected a warning that was accurately stated and properly supported by Merck. In support of this argument, Plaintiffs contend that Merck misstated the relevant risk in its PAS submission and the FDA's rejection of Defendant's proposed label is not clear evidence because the agency lacked information to make an informed judgment.

i. Warnings and Precautions Failure to Warn Analysis

Plaintiffs' argument that its claims are not preempted because clear evidence does not exist as to whether the FDA would have rejected a stronger warning to the Precautions section of the label is nothing more than an attempt to gain a second bite at the apple. Plaintiffs fail to raise any facts and/or arguments with regard to the Precautions section of the label that were not already considered and rejected by this Court. Plaintiffs assert that there is new evidence which was not before the Court in *Glynn* that changes the Precautions analysis; however, the "new evidence" provided by Plaintiffs is merely expert opinion on the very same evidence that existed in *Glynn*. Stated differently, while Plaintiffs were able to find an expert to agree with their contention that Merck should have acted differently with respect to updating the Precautions section of its warning, they did not set forth any evidence which suggests that *the FDA* thought the same. The evidence surrounding whether the FDA felt that a label change was necessary remains unchanged, and importantly, provides clear evidence that the FDA *would have* rejected a stronger Precautions warning because the FDA *did* reject a stronger Precautions warning. See *Glynn*, 2013 WL 3270387, at *7 ("the [fact that the] FDA never required Defendant to submit new language or change the label [ ] demonstrate[s] that the FDA did not think that the label should have been changed at that time.").

Plaintiffs further rely on this new expert opinion to argue that a fact question exists as to whether Merck should have warned about the risk of fractures associated with Fosamax by way of a CBE submission while the FDA decided on class labeling. Again, however, the Court already rejected this argument in *Glynn* and stated that "since the FDA rejected Defendant's PAS, it would not have approved a CBE seeking to add the same language to the label that it just

rejected in the PAS, and any changes Defendant made using the CBE supplement would cause the drug to be misbranded." *Id.* at *8.

Moreover, to the extent that Plaintiffs claim that Merck withheld information from the FDA and clear evidence does not exist as to whether the FDA, if fully informed, would have rejected a stronger label, this does not defeat Defendant's showing that it is entitled to judgment as a matter of law on preemption grounds. As an initial matter, Defendant disputes that it withheld information from the FDA; however, even assuming it did, Plaintiffs have failed to show that providing such information to the FDA would have changed the FDA's conclusion that a Precaution was not warranted. Instead, Plaintiffs' contention appears to be a fraud-on-the-FDA theory which was rejected by the Supreme Court in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001), or alternatively, is based largely on speculation and cannot defeat summary judgment. See *Webster v. Pacesetter, Inc.*, 259 F.Supp.2d 27, 37 (D.D.C. 2003) ("Nor can plaintiffs create an issue of fact regarding their defective warning claim by speculating that *if* the FDA had known of the delayed perforation and tamponade incidents during the clinical trials and *if* defendant had investigated all the adverse incidents, the FDA would have either recalled the lead or placed it on alert." (emphasis in original)); *In re Trasylol Products Liab. Litig.*, 2010 WL 4259332 (S.D. Fla. Oct. 21, 2010)("[An expert] may not speculate as to what the FDA would have done in hypothetical circumstances.").

Accordingly, Plaintiffs have failed to show that there is a genuine dispute of fact surrounding failure to warn claims based on the Precautions section of the label. Thus, these claims are preempted and Defendant is entitled to judgment as a matter of law.

IV. CONCLUSION

For the reasons outlined above, Defendant is entitled to judgment as a matter of law on all claims made by the Plaintiffs listed in Appendix A of the OTSC with injuries that occurred prior to September 14, 2010, because Plaintiffs have failed to show cause why their claims are not preempted under this Court's ruling in *Glynn*. An appropriate Order accompanies this Opinion.

Dated: March 26, 2014

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