UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

RAMONA LONGS, *as Executor of the Estate of Mary Buchanan,*	)	Case No.: 1:03 CV 2042
Plaintiff	)	
v.	)	JUDGE SOLOMON OLIVER, JR.
WYETH, *et al.*,	)	
Defendants	)	ORDER

Plaintiff Ramona Longs ("Plaintiff" or Longs") brings the above-captioned lawsuit as executor of the estate of decedent Mary Buchanan ("Buchanan"), alleging product liability claims regarding the diet pill Redux against Defendants Wyeth, *et al.* (collectively, "Defendants" or "Wyeth"). Now pending before the court are Plaintiff's Motion to Vacate Order and Judgment (ECF No. 151) and Plaintiff's Motion to Alter Judgment Pursuant to Federal Rule of Civil Procedure 59(e) (ECF No. 152). For the reasons discussed below, both Motions are denied.

I. FACTS AND PROCEDURAL HISTORY

A more detailed discussion of the facts appears in the court's Order of February 28, 2008. (Order, ECF No. 29.) In that Order, the court granted summary judgment in favor of Defendants on all of Plaintiff's claims, finding that the strict liability and negligence claims related to pre-FDA approval were preempted by federal law and that the claims that were not preempted failed on their merits. Specifically, the court held that Plaintiff's strict liability design defect claim failed because

Plaintiff had neglected to provide evidence to refute Defendants' showing that the Redux warnings were adequate as a matter of law. The court also held that Plaintiff's negligence claims failed because Plaintiff had neglected to provide evidence of proximate cause. The court then denied Defendants' Motions for Summary Judgment on Plaintiff's request for punitive damages as moot. By the same Order, the court also dismissed Plaintiff's failure to warn claim with prejudice on the ground that Plaintiff had voluntarily dismissed this claim. As a result of these rulings, the court dismissed Plaintiff's case in its entirety.

On March 10, 2008, Plaintiff filed the two pending Motions. In her Motion to Vacate Order and Judgment (ECF No. 151), Plaintiff requests that the court vacate its Order dismissing Plaintiff's case as well as its Judgment Entry for Defendants so that the court could consider Plaintiff's Motion to Alter Judgment (ECF No. 152). In her Motion to Alter Judgment, Plaintiff raises the following arguments: (1) Plaintiff's claims are not preempted; (2) Defendants bear the burden of proof regarding whether the warnings were inadequate; (3) Defendants did not properly raise the argument that Plaintiff lacked evidence of the inadequacy of warnings with regard to her design defect claim; and (4) Defendants did not properly raise the issue that Plaintiff lacked evidence of proximate cause related to her negligence claims.

II. STANDARD FOR ALTERING OR AMENDING JUDGMENT

Rule 59(e) motions may be granted in the following instances: (1) clear error of law; (2) newly discovered evidence; (3) an intervening change in controlling law; or (4) to prevent manifest injustice. *E.g., Gencorp, Inc. v. Am. Int'l Underwriters*, 178 F.3d 804, 834 (6th Cir. 1999). Although the court has authority to do so, a court will only reconsider its prior ruling in rare and unusual circumstances. As the court stated in *Dana Corp. v. United States*, 764 F. Supp. 482, 489

(N.D. Ohio 1991):

> Although 'motions to reconsider are not ill-founded step-children of the federal court's procedural arsenal,' they are 'extraordinary in nature and, because they run contrary to notions of finality and repose, should be discouraged.' *In re August,* 1993 Regular Grand Jury, 854 F. Supp. 1403, 1406 (S.D. Ind. 1994). To be sure, 'a court can always take a second look at a prior decision; but 'it need not and should not do so in the vast majority of instances,' especially where such motions 'merely restyle or re-hash the initial issues.' *Id.* at 1407. It is not the function of a motion to reconsider either to renew arguments already considered and rejected by a court or 'to proffer a new legal theory or new evidence to support a prior argument when the legal theory or argument could, with due diligence, have been discovered and offered during the initial consideration of the issue.' *Id.* at 1408. Where, as is the case with much of the instant motion, 'defendant views the law in a light contrary to that of this Court,' its 'proper recourse' is not by way of a motion for reconsideration 'but appeal to the Sixth Circuit.'

McConocha v. Blue Cross and Blue Shield Mut. of Ohio, 930 F. Supp. 1182, 1184 (N.D. Ohio 1996). Motions to reconsider are "not designed to give an unhappy litigant an opportunity to relitigate matters already decided, nor is it a substitute for an appeal." *Sherwood v. Royal Ins. Co. of Am.*, 290 F. Supp. 2d 856, 858 (N.D. Ohio 2003).

III. LAW AND ANALYSIS

A. Preemption

1. Pre-FDA Approval Claims

The court previously granted in part and denied in part Defendants' Motion for Partial Summary Judgment Based on Federal Preemption. (*See* Order, ECF No. 148, at 4-8.) Specifically, the court held that "all claims relating to pre-FDA approval are preempted by the FDA [or FDCA]. In addition, to the extent that Plaintiff alleges fraud-on-the-FDA or that Defendants concealed or misrepresented information to the FDA, these claims are preempted as well." (*Id.* at 6.) The court's conclusion was based on its finding that "Plaintiff's strict liability and negligence claims that Redux

was an 'unreasonably dangerous' drug for which no warning would have been adequate directly conflicts with the FDA's authority to determine which drugs are sufficiently safe and effective to be marketed." (*Id.*) However, the court also found that "Plaintiff's *post*-FDA approval design defect claims, under strict liability and negligence, are *not* preempted." (*Id.* at 7) (emphasis added.)

Plaintiff now argues that the court erred in finding that her claims relating to Defendants' conduct prior to the FDA's approval of Redux were preempted. In support of her argument for reconsideration, Plaintiff asserts that two recently decided Supreme Court cases bear on the preemption issues in the instant case. As discussed below, the court finds that these cases do not warrant a reconsideration of the court's original ruling on preemption.

In *Riegel v. Medtronic, Inc*, 128 S. Ct. 999 (Feb. 20, 2008), the plaintiff sued a medical device manufacturer for wrongful death, arguing that the device was defectively designed and labeled. The Court held that the Medical Device Act, 21 U.S.C. § 360k(a), expressly preempted common law claims regarding the safety and effectiveness of the device. The Court also noted that

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements. *Lohr*, 518 U.S., at 495, 116 S. Ct. 2240, 135 L. Ed. 2d 700; *see also id.*, at 513, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (O'Connor, J., concurring in part and dissenting in part).

Id. at1009 (internal quotations omitted). The Court only addressed the effect of the MDA on claims premised on violations of FDA regulations and did not address the extent to which tort claims are preempted by the FDCA. Furthermore, the Court expressly stated that, "[i]t has not been established (as the dissent assumes) that no tort lawsuits are pre-empted by drug or additive approval under the FDCA." *Id.* The Court left open the possibility that tort lawsuits are preempted to some extent

under the FDCA, but declined to fully address it as this was not an issue before the Court. Accordingly, *Riegel* did not establish whether Plaintiff's pre-FDA approval claims are preempted by the FDCA, as this issue was not before the Court.

In *Warner-Lambert Co., LLC v. Kent*, 128 S. Ct. 1168 (March 3, 2008) (per curiam), the court affirmed, without opinion, the decision in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006). *Kent* was affirmed by a 4-4 vote in which the Chief Justice abstained. As Defendants correctly note, "[a]ffirmance by an equally divided Court is entitled to no precedential weight." *In re Aredia & Zometa Prods. Liab. Litig.*, No. 3:06-MD-1760, 2008 U.S. Dist. LEXIS 26859 at *5 n.2 (M.D. Tenn. Apr. 2, 2008) (citing *Neil v. Biggers*, 409 U.S. 188, 192 (1972)). Accordingly, neither *Riegel* nor *Kent* are controlling in the instant case.

Furthermore, the Supreme Court's recently issued case, *Wyeth v. Levine*, No. 06-1249, 2009 U.S. LEXIS 1774 (U.S. Mar. 4, 2009), also does not support Plaintiff's Motion for Reconsideration. In *Wyeth*, the Court considered the narrow issue of "whether the FDA's drug labeling judgments preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." *Id.* at *13 (internal quotation omitted). The Court held that the FDA's approval of the defendant-drug manufacturer's label did not provide it a complete defense to the plaintiff's failure to warn claim, as the claim was not preempted by federal law. *Id.* In reaching its holding, the Court emphasized that it was Congress' intent to have state law complement federal drug regulation because "manufacturers have superior access to information about their drugs, *especially in the postmarketing phase as new risks emerge.*" *Id.* at *39 (emphasis added). The Court further noted the following:

> State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also

> serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, *in particular*, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

Id. at *39-*40 (emphasis added).

The instant case is distinguishable from *Wyeth* as this case does not involve a failure to warn claim, which served as the basis for the Supreme Court's determination. Furthermore, the court, in holding that a failure to warn claim is not preempted, focused on the fact that the claim arises out of the actions of the manufacturer post-FDA approval. The Court found that after the FDA approves a product for the market, manufacturers maintain a duty to update warning labels because of their superior knowledge of new risks concerning their products. *See id.* This post-FDA approval duty is distinguishable from a manufacturer's duty prior to approval by the FDA, a circumstance that the Court does not explicitly address. While *Wyeth* may stand for the proposition that post-FDA approval claims are preempted, it does not purport to hold that the same is true for pre-FDA approval claims. Thus, Plaintiff fails to demonstrate that this court erred in its holding that Plaintiff's pre-FDA approval claims are preempted.

2. Punitive Damages

Plaintiff also argues that her request for punitive damages is not preempted, relying again on *Kent*, 128 S. Ct. 1168. However, in its original Order, the court denied Plaintiff's request for punitive damages as moot based on its grant of summary judgment in Defendants' favor on all of Plaintiff's claims. (Order at 21, ECF No. 148.) Therefore, because the court never reached the issue

of whether Plaintiff's request for punitive damages is preempted, there is no issue for the court to reconsider.

B. Burden of Proof Regarding Adequacy of Warnings

Plaintiff argues that the court erred in finding that Plaintiff bears the burden of proving that the warnings were inadequate. However, Plaintiff fails to recognize that the court also found that "[e]ven assuming, *arguendo*, that Defendants bear the burden of proving that the Redux warnings were adequate, Defendants have presented sufficient evidence, which was uncontradicted by Plaintiff, to demonstrate that the warnings provided were adequate as a matter of law." (Order, ECF No. 148, at 12.) As such, the court's finding that Plaintiff bore the burden of proof regarding the adequacy of warnings was not essential to the court's granting of summary judgment in Defendants' favor. As discussed below, the court denies reconsideration of its finding that Defendants met any their burden of showing that the warnings were adequate as a matter of law. Therefore, the court need not revisit the burden of proof issue.

C. Design Defect Claim: Plaintiff's Lack of Evidence of Inadequacy of Warnings

Plaintiff contends that Defendants did not raise the argument that Plaintiff "lacked evidence of the inadequacy of warnings" regarding her design defect claim until their Reply Brief, and that therefore, the court committed clear error by ruling on that issue. As discussed below, the court finds that Plaintiff's argument is meritless and thus declines to reconsider its Order.

1. Defendants Properly Raised the Issue

First, the court finds that Defendants properly raised the issue of the adequacy of the Redux warnings in their initial Motion. In discussing Plaintiff's design defect claim, Defendants argued that "the record is clear that Wyeth, through its labeling and 'Dear Doctor' letters, provided an

adequate warning to physicians. Moreover, even if the warnings Wyeth provided to physicians were inadequate, plaintiffs have not established that any such claimed inadequacy proximately caused her physician to prescribe the drug to her." (Defs.' Mot. Summ. J. Based on Lack of Proximate Causation ("Defs.' Mot. Summ. J."), ECF No. 31, at 14) (emphasis added.)

In her Opposition Brief, Plaintiff acknowledged that Defendants had raised the issue of the adequacy of warnings by stating, "Wyeth argues that since it has evidence that the warnings were adequate, Redux 'cannot be found to be defectively designed.'" (Pl.'s Resp. to Wyeth's Mot. Summ. J. ("Pl's Resp."), ECF No. 39, at 1) (quoting Defs.' Mot. Summ. J. at 14.) Yet, with regard to this issue, Plaintiff argued only that "Wyeth has the burden of proving that the warnings were adequate under Ohio Rev. Code § 2307.75(D), and that issue remains a question of fact for the jury at trial." (*Id.* at 3.)[1] Despite expressly acknowledging that Defendants had raised the issue of the adequacy of warnings, Plaintiff did not present evidence to refute Defendants' argument that the evidence showed that the warnings were adequate as a matter of law. Plaintiff also did not argue that, if the court found that Plaintiff bore the burden of proving that the warnings were inadequate, Plaintiff could meet this burden.

Plaintiff also contends that Defendants argued only that "the warnings were adequate as a matter of law," and not that the opposing party "lacks evidence that the warnings were inadequate." The court finds that this argument is not well-taken. After Defendants had met their burden by

---

[1] Plaintiff also contended that Defendants' arguments regarding the failure to warn claim were moot because Plaintiff had voluntarily withdrawn that claim, and that Defendants' argument regarding the adequacy of warnings on the design defect claim were barred by *Mingus v. Wyeth*, No. 04-23744, 2006 WL 1071545 (E.D. Pa. Apr. 21, 2006). The court agreed that all arguments regarding the failure to warn claim were denied as moot, but the court rejected a finding that the *Mingus* opinion collaterally estopped Defendants in the within case. (Order, ECF No. 148, at 7-8.)

putting forth evidence that the warnings were adequate as a matter of law, Plaintiff, as the non-moving party on summary judgment, was required to "set forth specific facts showing that there is a genuine issue for trial" with regard to this issue. *See* Fed. R. Civ. P. 56(e). The court correctly determined in the previous Order that because Plaintiff failed to offer evidence to oppose Defendants' contention that the warnings were adequate as a matter of law, Defendants were entitled to a grant of summary judgment in its favor. As such, the court finds that Defendants properly raised the issue in their initial brief, thereby giving Plaintiff adequate opportunity to respond.

2. Plaintiff Misunderstands Her Burden on Summary Judgment

Second, the court finds that Plaintiff misunderstands her burden on summary judgment. Plaintiff admits that the volume of exhibits and evidence that she produced in support of her pending Motions were available during the summary judgment stage, yet Plaintiff failed to submit them to the court at that time in support of her Opposition Briefs. (Pl.'s Mot to Alter Judgment at 14, ECF No. 152.) Plaintiff has an affirmative duty to point out specific facts in the record to demonstrate that a genuine issue of material fact exists, which she failed to do. *See Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479-80 (6th Cir. 1989). Furthermore, because Plaintiff had access to this evidence at the time of briefing, Plaintiff cannot plausibly argue that this is newly discovered evidence. Accordingly, Plaintiff's argument that she has evidence to support her claim is not a basis for this court to reconsider its previous Order.

3. Plaintiff's Argument Is Untimely

Finally, the court finds that assuming, *arguendo*, that Defendants did not raise the issue of Plaintiff's lack of evidence until its Reply Brief, Plaintiff has waived this argument by neglecting to raise it until after the court ruled on summary judgment. If Plaintiff thought that Defendants were

improperly raising a new argument in their Reply Brief, Plaintiff could have moved to strike the argument or could have requested leave to file a surreply. Plaintiff could also have raised this issue during oral arguments, which were held on January 17, 2008 (more than two months after Defendants filed their Reply Brief, on November 1, 2007, and more than a month before the court issued its ruling, on February 29, 2008). Plaintiff did none of these things.

At oral arguments, Defendants opened by pointing out that:

> [T]he fact about the warnings has not been contested by the plaintiffs. There is no evidence that they put into the record which contests our evidence about the warnings.
>
> . . . .
>
> . . . [T]heir opposition papers are important as well and perhaps more important for what they don't do as for what they do. They do not insert any facts into the record contesting the adequacy of the warning that Wyeth gave, the various warnings, nor do they even argue, Your Honor, that the warnings were inadequate. They simply rested on the idea that we have the burden of proof.
>
> However, since they failed to contest the evidence that we submitted, we should win this case, we should win this motion irrespective of who has the burden. They simply did not contest the facts.

(Tr. of Proceedings, ECF No. 150, at 4, 6-7.) As such, Defendants put Plaintiff on notice at the beginning of oral arguments that they were using Plaintiff's failure to put forth evidence on the adequacy of warnings in support of their Motion for Summary Judgment. Instead of arguing that Defendants had improperly raised this argument, however, Plaintiff responded as follows:

> [L]et me make it clear from the beginning, the plaintiffs contend that no warning would have been adequate for this drug, and our experts say that.
>
> . . . [B]y withdrawing our claim of inadequate warning,[2] the burden of proof now shifts to the defendant.

---

[2] The court assumes that Plaintiff actually intended to say "claim of failure to warn," not "claim of inadequate warning."

> . . . .
>
> So what we intend to prove is that this drug was so dangerous and its benefits were so short term and small, that no warning would have been adequate, and therefore, it should have been taken off the market, it is off the market, and all we're trying to prove to the jury is that Wyeth should have withdrawn this drug from the market about a year sooner than it did.
>
> . . . .
>
> . . . [A]nd that's why the adequacy of the warning is not an issue that we have to face. If they want to raise it and try to prove that some warning would have been adequate, they're free to do so.
>
> . . . .
>
> . . . [W]e don't contend there is any adequate warning. We attack this drug as so defective that no warning would be adequate, and it shouldn't be on the market, so there's nothing for us to put forward in terms of a proper warning for this drug. The warning should have said: Don't take this drug for any purpose.
>
> . . . .

(*Id.* at 21-24.) As such, Plaintiff was aware of Defendants' argument regarding its warning and Plaintiff responded to the argument without presenting any challenge to it at that time.

As discussed previously, the court finds that Plaintiff's argument fails on its merits. The court further finds that Plaintiff's argument comes too late. Both the docket and the oral argument transcript make clear that, from the date of Defendants' Reply Brief until the court's Order granting summary judgment in favor of Defendants nearly four months later, Plaintiff never challenged Defendants' argument that Plaintiff lacked evidence of inadequate warnings, even though she had ample opportunity to do so if she wished. Instead, Plaintiff waited until the court had issued an adverse ruling before raising this argument. A party is not entitled to reserve particular issues and arguments until after a court rules against it. Courts have held that "[i]t is not the function of a motion to reconsider either to renew arguments already considered and rejected by a court or 'to proffer a new legal theory or new evidence to support a prior argument when the legal theory or argument could, with due diligence, have been discovered and offered during the initial

consideration of the issue.'" *Miller v. Norfolk S. Rwy. Co.*, 208 F. Supp. 2d 851, 852-53 (N.D. Ohio 2002) (quoting *In re August, 1993 Regular Grand Jury*, 854 F. Supp. 1403, 1408 (S.D. Ind. 1994)). Therefore, through what was perhaps a strategic move or a lack of diligence, Plaintiff has missed her opportunity to support her claim.

D. Negligence Claim: Plaintiff's Lack of Evidence of Proximate Cause

Plaintiff lastly argues that Wyeth did not raise that Plaintiff lacked evidence to support its negligence claim. However, Defendants specifically argued that Plaintiff's claims should fail based on a lack of evidence of proximate causation, which is an element of a negligence claim. The court agreed, stating that "Plaintiff has not bet her burden to defeat summary judgment because she has not presented evidence showing that Defendants' negligence proximately caused Plaintiff's injury or death." (Order at 19.) Although the court noted that it was unclear which theory of negligence she was purporting to argue, Plaintiff's failure to produce evidence regarding proximate cause was fatal to any claim of negligence. Plaintiff also argues that she has evidence to support this claim; however, as discussed above, Plaintiff may not proffer this evidence that she had at the time these Motions were filed. Thus, Plaintiff has failed to provide the court with a basis to alter its original judgment.

IV. CONCLUSION

For the reasons discussed above, Plaintiff's Motion to Vacate Order and Judgment (ECF No. 151) and Plaintiff's Motion to Alter Judgment (ECF No. 152) are both denied.

IT IS SO ORDERED.

/s/ *SOLOMON OLIVER, JR.*
UNITED STATES DISTRICT JUDGE

March 20, 2009