In the Superior Court of Pennsylvania

No. 5 EDM 2012

IN RE: REGLAN/METOCLOPRAMIDE LITIGATION

Petition of: Teva Pharmaceuticals USA, Inc.

ANSWER OF PLAINTIFFS/RESPONDENTS IN OPPOSITION TO THE PETITION FOR PERMISSION TO APPEAL

On Petition for Permission to Appeal from the November 18, 2011 Order, as Amended on December 16, 2011, of the Court of Common Pleas of Philadelphia County, Mass Tort Program, January Term 2010, No. 1997

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ANSWER OF PLAINTIFFS/RESPONDENTS IN OPPOSITION TO THE PETITION FOR PERMISSION TO APPEAL

I. INTRODUCTION

In *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011), the Supreme Court of the United States began its opinion by describing the precise question presented in the case, and the Court's resolution thereof, as follows:

> These consolidated lawsuits involve state tort–law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic metoclopramide. The question presented is whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre–empt, these state–law claims. We hold that they do.

Id. at 2572.

The U.S. Supreme Court issued its ruling in *Mensing* on June 23, 2011. In response to the Supreme Court's *Mensing* ruling, Plaintiffs' Liaison Committee filed the Third Amended Master Long Form Complaint in this case on August 1, 2011. That pleading purposefully omitted any claim that the manufacturers of generic metoclopramide should be held liable under state law for failing to include warnings that were different or in addition to the warnings that already appeared in the label for the brand name version of that medication.

Contrary to the Petitions for Permission to Appeal that the various generic drug manufacturers have filed in this case, in *Mensing* the Supreme Court of the United States *did not* issue a blanket holding that the manufacturers of generic prescription drugs can *never* be held liable under state law for any injuries sustained by patients who have consumed generic medications. Even more

importantly, the Supreme Court in *Mensing* also did not issue a blanket holding that generic drug manufacturers cannot never be held liable on a state law failure to warn claim.

Rather, *Mensing* held preempted by federal law one and only one type of state law claim: namely, the claim that the generic prescription drug manufacturer should be held liable under state law for failing to change the content of its warning label to adequately warn of the risks of the medication so that the generic manufacturer's label differed from the warning label that the FDA had approved for the brand name medication. Federal law preempted this state law failure to warn claim, the Supreme Court ruled, because under federal law the manufacturer of a generic prescription drug is required to use the same warning label that the federal Food and Drug Administration has approved for use by the brand name manufacturer of the prescription drug in question. Thus, in the Supreme Court's view, even if the warning label for brand name Reglan was inadequate to warn of that medication's risks, generic manufacturers of that medication were powerless to substitute a label containing different or additional warnings because federal law required that the generic warning label be "the same as" the brand name warning label for the medication at issue.

In this case, the presiding judge at the trial court level — the Honorable Sandra Mazer Moss, in her capacity as Coordinating Judge of Philadelphia's Complex Litigation Center — correctly recognized the limited scope of the U.S. Supreme Court's preemption ruling in *Mensing*. Judge Moss further correctly

recognized that plaintiffs' Third Amended Master Long Form Complaint did not advance the claim that the U.S. Supreme Court ruled in *Mensing* was preempted by federal law: namely, that generic manufacturers should have provided a label on the medications they manufactured containing warnings that differed from those appearing in the label that the FDA had approved for the brand name version of the drug. Judge Moss did not engage in a detailed claim by claim review of the various causes of action advanced in plaintiffs' Third Amended Master Long Form Complaint, because she correctly recognized that none of those claims was the same as the claim that the Supreme Court ruled was preempted in *Mensing*.

Judge Moss also correctly recognized that if the law of each plaintiff's home state would determine which specific claims each plaintiff could assert against the defendants, then determining whether *Mensing* would preempt the claims of a particular plaintiff would need to be decided on a state–by–state basis. As Judge Moss recognized, the appropriate time to undertake that labor intensive inquiry would be in the future, at the summary judgment stage, rather than at the preliminary objections stage when faced with the generic defendants' sweeping challenge to plaintiffs' Third Amended Master Long Form Complaint, a pleading applicable to all plaintiffs from anywhere within the United States who claim they were injured by Reglan and/or generic metoclopramide.

As explained in further detail below, the generic defendants have vastly overstated the preemptive effect of the U.S. Supreme Court's ruling in *Mensing*. Plaintiffs' Third Amended Master Long Form Complaint purposefully does not

allege the claim that the Supreme Court held was preempted by federal law in *Mensing*. Moreover, even if *Mensing* could somehow be read to hold that all state law failure to warn claims against generic prescription drug manufacturers were preempted by federal law — which *Mensing* clearly and unambiguously does not hold — plaintiffs' Third Amended Master Long Form Complaint nevertheless also contains claims against the generic manufacturers sounding in theories other than failure to warn. Thus, even if the generic defendants were correct that *Mensing* somehow precluded *all* failure to warn claims against generic manufacturers, those generic manufacturer defendants would still remain in the case, and be subject to discovery, on plaintiffs' other claims, which are not based on a failure to warn theory.

Judge Moss has made clear that she is willing to address on the merits, at an appropriate time, the generic defendants' argument that they are entitled to dismiss some or all of the claims contained in plaintiffs' Third Amended Master Long Form Complaint under the generic defendants' improperly broad and ambitiously aggressive view of the consequences of the U.S. Supreme Court's ruling in *Mensing*. All that Judge Moss has correctly recognized thus far, however, is that taking *Mensing* at face value as holding preempted only the specific variety of failure to warn claim that was at issue in *Mensing*, and recognizing that the plaintiffs here are not asserting that specific type of failure to warn claim, the *Mensing* decision on its face does not dictate the dismissal of any of plaintiffs' claims contained in the Third Amended Master Long Form Complaint.

In sum, the Petitions for Permission to Appeal do not involve a "controlling question of law" because regardless of the scope of *Mensing*, plaintiffs' other, non–warning based claims against the generic manufacturers will remain for trial. Similarly, because even if the generic manufacturer defendants were to prevail in this interlocutory appeal they would achieve only the dismissal of a subset of claims against them and the dismissal of none of the claims against the brand name manufacturer defendants, allowing an interlocutory appeal by permission would not materially advance the ultimate termination of this matter. For all of these reasons, which are addressed in more detail below, the Petitions for Permission to Appeal should be denied.

II. CONCISE STATEMENT OF THE CASE

On June 23, 2011, the Supreme Court of the United States issued its ruling in *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011). In *Mensing*, the U.S. Supreme Court ruled that federal law preempted a state court failure to warn claim against the manufacturer of a generic prescription drug where the claim is predicated on the theory that the generic manufacturer should have altered the warning label of the medication to provide an adequate warning that differed from the FDA approved warning label for the brand name version of the drug. The Supreme Court anchored its holding on a recognition that federal law requires that the warning label for a generic medication must be the same as the FDA–approved warning label for the brand name version of the drug in question. Because, under federal

law, the manufacturer of a generic medication is precluded from altering the medication's warning label to add whatever additional or different warning that state law would require for the warning label to be adequate, the Supreme Court ruled that federal law preempts state law failure to warn claims challenging the adequacy of a generic medication's warning label where that warning label was in fact identical to the warning label that the FDA had approved for the brand name medication.

On August 1, 2011, more than one month after the U.S. Supreme Court had issued its ruling in the *Mensing* case, the Plaintiffs' Liaison Committee filed the Third Amended Master Long Form Complaint in this case. That Third Amended Master Long Form Complaint purposefully omits any claim that the manufacturers of generic metoclopramide should be held liable under state law for failing to alter the warning label for that medication to contain warnings different from or in addition to the warnings that the FDA had approved for the brand name version of the medication.

The Third Amended Master Long Form Complaint contains 16 claims for relief. The defendants named in that complaint consist of both the brand name manufacturers of Reglan and the generic manufacturers of metoclopramide, which is the active ingredient in Reglan. The specific claims for relief contained in plaintiffs' Third Amended Master Long Form Complaint are: count one – strict product liability failure to warn; count two – strict product liability design defect; count three – negligence; count four – negligence *per se*; count five – fraud and

intentional misrepresentation; count six – constructive fraud; count seven – breach of express and implied warranties; count eight – unfair and deceptive trade practices; count nine – unjust enrichment; count 10 – conscious or negligent misrepresentation; count 11 – civil conspiracy; count 15 – gross negligence/malice; count 16 – punitive damages. Counts 12 through 14 assert claims for loss of consortium, wrongful death, and survival, respectively.

The only failure to warn claims based on a failure to change the medication's warning label to adequately warn of the medication's actual risks asserted in plaintiffs' Third Amended Master Long Form Complaint are asserted against the brand name manufacturers of Reglan, manufacturers against which federal law does not preempt such state law negligent failure to warn claims. *See Wyeth* v. *Levine*, 555 U.S. 555 (2009).

In accordance with the U.S. Supreme Court's ruling in *Mensing*, however, plaintiffs' Third Amended Master Long Form Complaint does not assert any such claims against the generic manufacturers of metoclopramide which, as generic manufacturers, are required under federal law to place on their medication the same warning label that the FDA has approved for the brand name version of the medication.

Accordingly, only two types of failure to warn claims are asserted against the generic manufacturers of metoclopramide in plaintiffs' Third Amended Master Long Form Complaint. The first type asserts that the generic manufacturers of metoclopramide waited too long after the FDA approved a stronger and more

detailed warning label for brand name Reglan to begin to apply that identical warning label to generic metoclopramide. Federal law would not preempt this type of a claim, because it merely seeks to enforce the federal law requirement that the warning label for generic metoclopramide be identical to the warning label that the FDA has approved for the brand name medication.

The second type of warning claim asserts that the manufacturers of generic metoclopramide should have communicated FDA–approved warnings added to the label for brand name Reglan but which were never communicated by *any* manufacturer — generic or brand — to the physicians prescribing the drug or to those consuming the medication. Plaintiffs have alleged that the generic defendants knew or reasonably should have known that the Physicians' Desk Reference publication on which prescribing doctors ordinarily rely in deciding whether to prescribe a given medication never included stronger and more detailed warnings approved by the FDA for the brand name version of the medication. Thus, this second type of warning claim asserts that these generic manufacturers should have used readily available means to alert those physicians to the existence of new, stronger, and more detailed warnings that the FDA had approved for the brand name medication. Again, because the warnings in question had already been FDA approved for the brand name medication, this second theory does not seek to impose on generic manufacturers a duty to adopt warning labels that differ from the warning label that was FDA approved for use on the brand name medication.

The remaining categories of claims asserted against the generic manufacturers of metoclopramide in the Third Amended Master Long Form Complaint are even further removed from the specific sort of state law negligent failure to warn claim that was at issue in *Mensing*. The claims advanced in plaintiffs' Third Amended Master Long Form Complaint that the *Mensing* decision most obviously could not impact allege design defect; fraud and intentional misrepresentation; negligent misrepresentation; breach of express and implied warranties; unfair and deceptive trade practices; and unjust enrichment. The existence of these claims is of paramount significance, because even if this Court were to disagree with Judge Moss over the scope of *Mensing*'s preemptive effect with regard to state law failure to warn claims, the generic defendants would remain parties to this lawsuit on these other, non–failure to warn claims, and thus the question on which the generic defendants request permission to appeal is neither "controlling" nor would its resolution "materially advance the ultimate termination" of this matter.

On November 18, 2011, Judge Moss issued her decision denying the generic defendants' preliminary objections seeking to dismiss all of the claims asserted against the generic defendants in plaintiffs' Third Amended Master Long Form Complaint based on the defense of federal preemption in the aftermath of *Mensing*. In a well–reasoned six–page opinion, Judge Moss correctly noted that a demurrer can only be granted under Pennsylvania law if "the law says with certainty that no recovery is possible." Opinion at 2 (quoting *Employers Ins. of Wausau* v.

Commonwealth, Dep't of Transp., 581 Pa. 381, 388 n.5, 865 A.2d 825, 829 n.5 (2005)).

Judge Moss's opinion proceeded to note that the U.S. Supreme Court's decision in *Mensing* focused solely and specifically on a claim that state law required the manufacturer of a generic medication to use a warning label on the drug that differed from the warning label that the FDA had approved for the brand name version of the drug in question. Judge Moss further recognized that the U.S. Supreme Court ruled in *Mensing* that federal law preempted such a state law claim because federal law required that the generic manufacturer use the identical warning label on the medication that the FDA had approved for the brand name version of the medication.

Judge Moss then summarized plaintiffs' argument in opposition to the generic manufacturers' preliminary objections as follows:

> [Plaintiffs] argue the *Mensing* Court foreclosed only claims requiring generic manufacturers to unilaterally change their drug's warning label to include information different from and additional to the brand manufacturer's approved FDA label. Plaintiffs contend only in such situations would it be impossible for generic manufacturers to comply with both federal and state law and, further, *Mensing* does not insulate Defendants from state law duties not requiring label changes. Plaintiffs assert because their amended complaint asserts only theories not requiring label changes, *Mensing* does not affect their claims.
>
> Plaintiffs argue Defendants should have more effectively communicated their FDA approved label to the medical community, engaged in risk minimization strategies and/or suspended drug sales. They additionally argue FDA approved label changes in 2003 (warning use in geriatric patients) and 2004 (warning therapy should not exceed 12 weeks) were never included on some generic manufacturers' labels and were never communicated to the larger medical community because the *Physicians Desk Reference* (PDR) contained the 2002

> metoclopramide label only. Plaintiffs conclude since the *Mensing* Court failed to consider the aforementioned theories, their claims are not preempted.

Opinion at 3–4 (citations omitted). For the Court's convenience, a copy of Plaintiffs' Memorandum of Law in Support of their Response in Opposition to the Master Preliminary Objections of Generic Defendants to Plaintiffs' Third Amended Complaint is attached hereto as Exhibit A.

In her opinion, Judge Moss next undertook a review of some of the numerous decisions from other courts applying *Mensing* to lawsuits brought by plaintiffs alleging personal injuries as the result of having ingested generic prescription medications. Judge Moss recognized that the arguments plaintiffs were advancing for why *Mensing* does not foreclose their failure to warn claims have been repeatedly recognized as valid by numerous other courts in *Mensing*'s aftermath. Opinion at 5. In concluding that the generic defendants' preliminary objections should be denied, Judge Moss explained that "[w]e find Defendants have failed to sustain this 'heavy burden' to show with certainty there is no legal recovery." *Id.*

As an alternate basis for denying the generic defendants' preliminary objections, Judge Moss explained that the Philadelphia Court of Common Pleas had ruled in the Hormone Replacement Therapy mass tort litigation that a rebuttable presumption existed that a plaintiff's home state law would govern the plaintiff's personal injury claims. Because the plaintiffs in this case, as in the HRT litigation, reside throughout the nation, Judge Moss recognized that it would be necessary on a state–by–state basis to determine what types of personal injury claims against

generic drug manufacturers were available under applicable state law in a given case before deciding whether the U.S. Supreme Court's decision in *Mensing* would preclude such claims due to federal preemption. Judge Moss's ruling in this regard is directly supported by the language of the *Mensing* decision itself, which acknowledged that "[p]re–emption analysis requires us to compare state and federal law." *Mensing*, 131 S. Ct. at 2573.

Judge Moss's opinion confirms that, at most, *Mensing* only could affect some or all of plaintiffs' failure to warn claims against the generic defendants, and thus, even if defendants were correct, plaintiffs would still possess numerous other claims against the generic defendants that were not subject to federal preemption under *Mensing*. Moreover, as Judge Moss further recognized, the *Mensing* arguments do not affect any of the plaintiffs' claims against the brand name manufacturers of Reglan, and thus those claims would likewise remain in this case.

On December 16, 2011, Judge Moss issued an order that amended her order dated November 18, 2011 to include the language specified in 42 Pa. Cons. Stat. Ann. §702(b) to authorize an interlocutory appeal by permission. In accordance with that statutory provision, however, before an interlocutory appeal by permission may be taken, this Court must likewise grant permission for the appeal to proceed. For the reasons that follow, this Court should deny the generic defendants' petition for permission to appeal.

III. REASONS WHY PERMISSION TO APPEAL SHOULD BE DENIED

A. The Generic Defendants Cannot Satisfy Two Of The Necessary Requirements For Taking An Interlocutory Appeal By Permission

The generic defendants are asking this Court to allow them to take an interlocutory appeal by permission pursuant to 42 Pa. Cons. Stat. Ann. §702(b), which states, in full:

> **Interlocutory appeals by permission.**—When a court or other government unit, in making an interlocutory order in a matter in which its final order would be within the jurisdiction of an appellate court, shall be of the opinion that such order involves *a controlling question of law* as to which there is substantial ground for difference of opinion and that *an immediate appeal from the order may materially advance the ultimate termination of the matter*, it shall so state in such order. *The appellate court may thereupon, in its discretion, permit an appeal to be taken from such interlocutory order.*

Id. (emphasis added). The standard for allowing an appeal under this statutory provision is, in all relevant respects, identical to the federal interlocutory appeal by permission statute codified at 28 U.S.C. §1292(b).

In order for an interlocutory appeal by permission to proceed forward under 42 Pa. Cons. Stat. Ann. §702(b), not only must the trial court grant permission, but this Court must additionally and independently also grant permission. *See Commonwealth* v. *Harris*, 32 A.3d 243, 250 (Pa. 2011) (recognizing that *both* the trial court *and* the appellate court must grant permission for an interlocutory appeal by permission to proceed); *Geniviva* v. *Frisk*, 555 Pa. 589, 599 n.5, 725 A.2d 1209, 1214 n.5 (1999) ("this procedure invokes the exercise of discretion by both the initial tribunal and the appellate court").

In *Kensey* v. *Kensey*, 877 A.2d 1284 (Pa. Super. Ct. 2005), this Court explained:

> 42 Pa.C.S.A. §702 permits this Court "in its discretion" to entertain an appeal of an interlocutory order if it is satisfied with the trial court's certification that there is a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the matter.

Id. at 1289. In *Kensey*, this Court agreed with the trial court that the order in question presented a controlling question of law as to which there is a substantial ground for difference of opinion, but this Court nevertheless *denied permission* to appeal because "we do not view an immediate appeal as materially advancing the ultimate termination of this matter." *Id.*; *see also Miller* v. *Krug*, 386 A.2d 124, 127 (Pa. Super. Ct. 1978) (denying petition for permission to appeal because "we disagree with the lower court that the certified question meets the criteria" for an interlocutory appeal by permission).

In this case, as plaintiffs now turn to demonstrate, the question of law that the generic manufacturer defendants have asked this Court to review does not constitute a "controlling" question of law, nor would this Court's resolution of that question at this time "materially advance the ultimate termination" of this matter. Accordingly, this Court should deny the generics defendants' petition for permission to appeal.

B. The Question The Generic Defendants Have Proposed For Review Does Not Constitute A "Controlling" Question Of Law

In order for a question of law to qualify as "controlling," the question must be "serious to the conduct of the litigation, either practically or legally." *See Johnson* v. *Burken*, 930 F.2d 1202, 1206 (7th Cir. 1991) (internal quotations omitted). As demonstrated below, the question that the generic defendants have proposed for resolution does not qualify as "controlling" because the precise claim that the U.S. Supreme Court ruled was preempted under federal law in *Mensing* is not among the claims that plaintiffs are asserting against the generic defendants in the Third Amended Master Long Form Complaint. Moreover, even if *Mensing* could be read to preempt *all* state law failure to warn claims against generic drug manufacturers — which it cannot — the plaintiffs' remaining, non–failure to warn claims against the generic defendants asserted in Third Amended Master Long Form Complaint would nevertheless survive unaffected. And, it goes without saying, that all of the claims against the brand name manufacturers would be unaffected by this Court's consideration and resolution of the scope of federal preemption of failure to warn claims against generic drug manufacturers in the aftermath of *Mensing*.

The central basis for the generic defendants' assertion that this Court should grant permission for this interlocutory appeal to proceed is the claim that the U.S. Supreme Court's decision in *Mensing* held that generic defendants cannot be held liable under any state law theory for injuries that patients have sustained as the result of ingesting generic prescription drugs. The generic defendants' argument in

this regard, to put it mildly, represents a gross overstatement of the scope of the U.S. Supreme Court's actual holding in *Mensing*.

Plaintiffs respectfully urge the Judges of this Court who are considering these petitions for permission to appeal to actually take a look at the U.S. Supreme Court's ruling in *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011), before deciding whether to grant permission to appeal, because any review of that ruling will make it perfectly clear that the generic defendants' claim that *Mensing* precludes *all* state law failure to warn claims is utterly and undeniably false. In *Mensing*, the Supreme Court of the United States *did not* rule explicitly or implicitly that the manufacturers of generic prescription drugs can *never* be held liable under state law for any injuries sustained by patients who have consumed generic prescription drugs.

Even more importantly, the Supreme Court in *Mensing* also did not issue a blanket holding that generic drug manufacturers cannot never be held liable on a state law failure to warn claim. Rather, *Mensing* held preempted by federal law *one and only one* type of state law claim: namely, the claim that the generic prescription drug manufacturer should be held liable under state law for failing to provide a warning label that contained warnings that were either different from or in addition to the warnings appearing in the label that the FDA had approved for the brand name version of the medication. Indeed, the majority opinion in *Mensing* carefully used the term "warning label" a total of eleven times, purposefully limiting the

scope of the Court's holding in that case to the one and only specific type of state law failure to warn claim that the Court had granted review to consider.

Federal law preempted the particular state law failure to warn claim at issue in *Mensing*, the Supreme Court ruled, because under federal law the manufacturer of a generic prescription drug is required to use the same warning label that the federal Food and Drug Administration has approved for use by the brand name manufacturer of the prescription drug in question. Thus, in the Supreme Court's view, even if the warning label for brand name Reglan was inadequate to warn of that medication's risks, generic manufacturers of that medication were powerless to substitute a different warning label because federal law required that the generic warning label be the same as the brand name warning label for the medication at issue.

This understanding of the scope of the U.S. Supreme Court's ruling in *Mensing* flows directly from the language of that ruling:

> "[Plaintiffs] claimed that 'despite mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than that indicated on the label,' none of the Manufacturers had changed their label to adequately warn of that danger."
>
> "The parties do not dispute that, if these allegations are true, state law required the Manufacturers to use a different, safer label."
>
> "What is in dispute is whether, and to what extent, generic manufacturers may change their labels *after* initial FDA approval."
>
> "Taking Mensing and Demahy's allegations as true, this duty required the Manufacturers to use a different, stronger label than the label they actually used."

> "If the manufacturers had independently changed their labels to satisfy their state–law duty . . ."
>
> "Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action."

Mensing, 131 S. Ct. at 2573, 2574, 2577, 2578, 2581.

As Judge Moss correctly observed in her opinion denying the generic defendants' preliminary objections, the precise claim that the U.S. Supreme Court ruled was preempted in *Mensing* is not at issue in this case, because the Third Amended Master Long Form Complaint that plaintiffs filed over a month after the *Mensing* decision issued purposefully omitted any such claim against the generic drug manufacturer defendants. Rather, the only claims asserted against the generic drug manufacturers in plaintiffs' Third Amended Master Long Form Complaint are claims that *Mensing* did not hold to be preempted under federal law. Moreover, a large variety of claims against the generic drug manufacturers advanced in plaintiffs' Third Amended Master Long Form Complaint are not even failure to warn claims.

Judge Moss's decision denying the generic defendants' preliminary objections asserting federal preemption under *Mensing* was and remains well within the judicial mainstream. For example, in *Couick* v. *Wyeth, Inc.*, 2012 WL 79670 (W.D.N.C. 2012), a federal district court denied a motion filed by the manufacturers of generic metoclopramide to dismiss a product liability claim alleging that those manufacturers were liable under state law for failing to change their medication's warning label to mirror the more explicit warning label that the FDA had approved

for brand name Reglan. *Id.* at *3–5. That same federal district court also refused to dismiss as preempted under *Mensing* plaintiff's claims for breach of express and implied warranties. *Id.* at *5–*7.

In another post–*Mensing* generic metoclopramide decision, a federal district court in *Brasley–Thrash* v. *Teva Pharmaceuticals USA, Inc.*, 2011 WL 4025734 (S.D. Ala. 2011), rejected the defendants' argument that under *Mensing* federal law would preempt a plaintiff's state law claim that the manufacturers of that generic medication should have done a more effective job of communicating to health care providers the FDA approved warnings for brand name Reglan. *See id.* at *2–*3.

And, in *Fisher* v. *Pelstring*, 2011 WL 4552464 (D.S.C. 2011), a third post–*Mensing* generic metoclopramide decision, a federal district court concluded that federal law did not preempt the plaintiffs' claims for: (1) failure to warn based on the allegation that the generic manufacturers did not include on the warning labels of their products the updated, strengthened warnings that the FDA had approved for brand name Reglan in 2003 and 2004, *see id.* at *2–*3; (2) breach of implied warranties, *see id.* at *17–*19; (3) fraudulent concealment, *see id.* at *20; and (4) unfair trade practices, *see id.* at *21–*22. Even more recently, on January 11, 2012, this very same federal district court issued a follow–up decision denying the generic manufacturer's motion to reconsider these specific *Mensing*–related rulings. *See Fisher* v. *Pelstring*, No. 04:09–cv–252–TLW (D.S.C. Jan. 11, 2012).

As this Court explained in *Lance* v. *Wyeth*, 4 A.3d 160, 164 (Pa. Super. Ct. 2010), *alloc. granted*, 15 A.3d 429 (Pa. 2011), there are three distinct types of claims

that can be asserted against the manufacturer of a product for injuries resulting from the use of that product: (1) manufacturing defect; (2) design defect; and (3) warning defect. In *Lance*, this Court recognized that a claim for negligent design defect is distinct from a claim for negligent failure to warn, and this Court ruled that a negligent design defect claim can be brought under Pennsylvania law against the manufacturer of a prescription drug. *See* 4 A.3d at 164, 166. Indeed, plaintiff's Brief for Appellee filed in the *Lance* case before the Supreme Court of Pennsylvania explains that no state in the nation has prohibited a plaintiff from bringing a negligent design defect claim against the manufacturer of a prescription drug.

Here, plaintiffs' Third Amended Master Long Form Complaint asserts both claims for negligent design defect and strict liability design defect against the manufacturers of generic metoclopramide. The U.S. Supreme Court's ruling in *Mensing* did not consider whether, and therefore most assuredly did not hold that, such a design defect claim would be preempted under federal law. Plaintiffs' claim that the generic manufacturers should have refrained from offering generic metoclopramide for sale under a design defect theory because the medication's actual risks outweighed the medication's actual usefulness is not preempted by federal law, because while federal law allowed the generic manufacturers to offer the drug for sale, federal law did not affirmatively mandate that they must sell the drug regardless of whether the drug's risks outweighed its benefits.

Similarly, *Mensing* did not consider or hold that federal law would preempt plaintiffs' claims against the generic drug manufacturers for fraud and intentional

misrepresentation; breach of express and implied warranties; and unjust enrichment. Thus, even if the generic defendants were correct that *Mensing* could somehow be read to prohibit any claims sounding in negligence against generic prescription drug manufacturers — which the *Mensing* decision unquestionably cannot be understood to hold — plaintiffs would still have a wide variety of claims against the generic defendants that remained for adjudication in this lawsuit.

As a result, the question that the defendants have asked this Court to grant permission to appeal is both based on a gross and unjustifiable misreading of *Mensing* and fails to present a "controlling" question because, regardless of how that issue is resolved, the generic defendants will still be required to undergo discovery and further proceedings. In this case, failure to warn claims against the generic defendants represent only one type of claim against those defendants and a small subset of all of the claims that are at issue in this litigation against both the brand name and generic prescription drug manufacturer defendants. Accordingly, this Court should deny the petition for permission to appeal.

C. Granting Permission To Appeal To Determine The Impact Of *PLIVA, Inc.* v. *Mensing* On Plaintiffs' Third Amended Master Long Form Complaint Would Not "Materially Advance The Ultimate Termination" Of This Matter

The generic defendants' petition for permission to appeal should also be denied because allowing an interlocutory appeal by permission at this time to determine the impact of *PLIVA, Inc.* v. *Mensing* on plaintiffs' Third Amended

Master Long Form Complaint would not "materially advance the ultimate termination" of this case.

The issue is not whether the generic defendants will be entitled to appellate review of the trial court's application of *Mensing* in this case to determine if any of the claims in plaintiffs' Third Amended Master Long Form Complaint are preempted by federal law. Of course they will be entitled to such appellate review, assuming that the generic defendants remain aggrieved by the trial court's ultimate rulings on that issue, which certainly could favor either the plaintiffs or the generic defendants when the trial court ultimately issues a final and authoritative ruling on the matter.

Rather, the question that this Court must now confront is whether allowing an interlocutory appeal by permission now — when the trial court proceedings have just passed the preliminary objection stage — would further the purpose of the interlocutory appeal by permission statute by "materially advanc[ing] the ultimate termination" of this case if the generic defendants were to prevail on appeal.

Taking the U.S. Supreme Court's ruling in *Mensing* at face value, as Judge Moss properly did by focusing on the one and only claim at issue in that case — a claim that required a generic manufacturer to use a different and stronger warning label than had been approved by the FDA — allowing an interlocutory appeal by permission at this time would serve no purpose other than unjustified delay, because that particular type of failure to warn claim is not asserted against the

generic manufacturer defendants in plaintiffs' Third Amended Master Long Form Complaint.

Moreover, if this Court were to take a broader view of the preemptive effect of the *Mensing* decision as holding, contrary to *Mensing*'s cautious and purposefully limited language, that federal law somehow preempted any and all state law failure to warn claims against the manufacturer of a generic prescription drug, even such a ruling by this Court would not result in the dismissal of all of plaintiffs' claims contained in the Third Amended Master Long Form Complaint against the generic defendants, because plaintiffs' claims against the generic manufacturers in this case are not limited to claims alleging a failure to warn.

Thus, only if this Court were to somehow conclude that *Mensing* holds that federal law preempts any and all state tort law claims against the manufacturer of generic prescription drugs — a holding that *Mensing* in no conceivable way can be understood to support — would it even be theoretically possible that granting permission to appeal could result in the dismissal of all of plaintiffs' claims against the generic defendants contained in the Third Amended Master Long Form Complaint.

Because there is absolutely no possibility that this Court's application of the U.S. Supreme Court's decision in *Mensing* to plaintiffs' Third Amended Master Long Form Complaint could result in the dismissal of all of plaintiffs' claims against the generic manufacturer defendants, those defendants are unable to establish that

allowing this interlocutory appeal by permission may materially advance the ultimate termination of this case.

As federal appellate judge Richard A. Posner of the U.S. Court of Appeals for the Seventh Circuit has cogently observed, the interlocutory appeal by permission statute "was not intended to make denials of summary judgment routinely appealable." *Ahrenholz* v. *Board of Trustees of University of Ill.*, 219 F.3d 674, 676 (7th Cir. 2000). Simply put, deciding whether only one type of claim (failure to warn claims) against only one type of defendant (generic drug manufacturers) can or cannot survive the U.S. Supreme Court's ruling in *Mensing* is not an issue whose resolution would materially advance the ultimate termination of this case where other claims against generic drug manufacturers clearly do survive *Mensing* and where that question in no way affects plaintiffs' claims against the brand name drug manufacturer defendants.

Finally, as the alternate basis for her decision denying the generic defendants' preliminary objections based on *Mensing*, Judge Moss recognized that it would make the most sense to resolve the issue of preemption on a state–by–state basis, because the resolution of the preemption issue depends on precisely what types of personal injury claims applicable state law recognizes against the manufacturer of a prescription drug. The generic defendants' attempt to ridicule Judge Moss's conclusion in that regard lacks merit, because the U.S. Supreme Court's ruling in *Mensing* itself recognizes that before one can decide whether federal law preempts a state law cause of action under principles of conflict

preemption, it is necessary to ascertain under state law the precise duty that the plaintiff is seeking to impose on the defendant. After that duty is determined, it is then possible to examine whether imposing that duty would unavoidably conflict with the obligations that federal law places on that same defendant. *See Mensing*, 131 S. Ct. at 2573 ("Pre–emption analysis requires us to compare federal and state law. We therefore begin by identifying the state tort duties and federal labeling requirements applicable to the Manufacturers.").

Different states, as is their prerogative, allow or disallow different types of tort claims to be asserted by personal injury claimants against prescription drug manufacturers. As Judge Moss recognized, it makes the most sense to determine what theories of liability are available to a plaintiff under the law applicable to that plaintiff's claims before deciding whether *Mensing* does or does not preempt such claims.

As an appellate court, the Superior Court of Pennsylvania is a court of review, not a Court of first view. *Cf. Cutter* v. *Wilkinson*, 544 U.S. 709, 718 n.7 (2005) ("we are a court of review, not of first view"). Undertaking the *Mensing* inquiry at this time, if Judge Moss is correct about the preferred method of proceeding, would require this Court to examine the law of all 50 states, the District of Columbia, and various U.S. Territories, all without any assistance from the trial court judge, to whom resolution of issues of this nature are assigned in the first instance. Certainly that inquiry would be lengthy and complex, and having this

Court undertake it in the first instance at this time certainly would not "materially advance the ultimate termination" of this matter.

Separately, the generic defendants' effort to appeal without permission, under the collateral order doctrine, Judge Moss's denial of their preliminary objections alleging *Mensing* preemption likewise clearly lacks merit. Plaintiffs therefore plan to promptly file a motion seeking the dismissal of those appeals, because orders rejecting a claim of federal preemption of state law do not qualify as final orders under the collateral order doctrine. *See*, *e.g.*, *Jordan* v. *AVCO Fin. Servs. of Ga., Inc.*, 117 F.3d 1254, 1258 (11th Cir. 1997) (dismissing for lack of appellate jurisdiction a collateral order appeal of denial of a motion to dismiss after concluding that "the [McCarran–Ferguson] Act is a statute of preemption rather than one granting immunity"); *Wood* v. *United States*, 995 F.2d 1122, 1130 (1st Cir. 1993) (en banc) (holding that "interlocutory appeal did not lie from the district court's decision" on "whether or not federal law preempted certain of Wood's state law claims"), *abrogated on other grounds by Osborn* v. *Haley*, 549 U.S. 225 (2007).

* * * * *

The generic defendants' petition for permission to appeal vastly overstates the limited impact of the U.S. Supreme Court's narrow preemption ruling in *Mensing* and thus incorrectly describes the impact that the *Mensing* ruling might have in this case, which actually ranges from little to no impact. As a result, the question presented for review, in the context of this case, does not constitute a "controlling" question of law, nor would an immediate appeal "materially advance

the ultimate termination" of this vast litigation. Rather, an immediate appeal would only serve to unjustifiably delay the ability to achieve redress of many thousands of seriously injured plaintiffs. Under the circumstances of this case, as in the overwhelming majority of cases, appellate review of orders denying a motion to dismiss simply should and must await the entry of a final judgment.

IV. CONCLUSION

For the reasons explained above, this Court should deny the generic defendants' petition for permission to appeal.

Respectfully submitted,

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IN RE	:	
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REGLAN/METOCLOPRAMIDE	:	PHILADELPHIA COUNTY
LITIGATION	:	
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PLAINTIFFS	:	JANUARY TERM, 2010
	:	NO.: 01997
Plaintiffs,	:	
	:	
vs.	:	
	:	
WYETH LLC, *et al.*,	:	
	:	
Defendants.	:	

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR RESPONSE IN OPPOSITION TO THE MASTER PRELIMINARY OBJECTIONS OF GENERIC DEFENDANTS TO PLAINTIFFS' THIRD AMENDED COMPLAINT

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I. INTRODUCTION

Despite repeated instruction from the United States Supreme Court that courts should not resolve questions of preemption based upon the descriptive title given to a Plaintiffs' claims, Generic Defendants attempt to shoehorn all of the claims against them under the name "failure to warn." Their attempt fails. It is clear from the allegations appearing within Plaintiffs' Third Amended Master Long Form Complaint ("TAMLFC") that Plaintiffs' claims against the Generic Defendants are based not only on the warnings that they failed to provide to prescribing physicians and consumers, but also on the false and misleading statements they made regarding these products, their blatant violation of federal statutes and regulations enacted by Congress' for the protection of consumers such as Plaintiffs, and their actions of selling a dangerous and ineffective drug (for decades) for the sake of their profit margin.

Even so, as the Supreme Court has instructed, in performing a preemption analysis, one must first determine "the legal duty that is the predicate of the common law damages action" in order to determine whether such a claim is preempted. *Altria Group, Inc. v. Good*, 129 S.Ct. 538, 545 (2008), citing *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608 (1992). In *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), the Supreme Court performed a preemption analysis with respect to a state law duty of a generic manufacturer "to use a different, stronger label than the label they actually used." *Id* at 2577. While the *Mensing* decision addressed only this one specific duty, Generic Defendants argue that the Court's ruling dictates that *no* duty may be placed upon a generic manufacturer. Their argument abandons logic and reason, and conflicts directly with the entirety of the Supreme Court's preemption case law.

Since the inception of the present litigation, Plaintiffs have at all times alleged that the Generic Defendants violated numerous duties imposed upon them by both state and federal law.

In their Preliminary Objections, Generic Defendants accuse Plaintiffs of making only slight changes to the previous versions of the long form complaint. The reason for this is simple – *Mensing* spoke only to a single claim out of the many that Plaintiffs' have consistently asserted. Despite the efforts of Generic Defendants to convince the Court that *Mensing* bars Plaintiffs' from pursuing any of their claims, the language of the opinion clearly indicates that its holding applies only to claims that a generic manufacturer should have unilaterally changed the content of the label for its prescription drug product.

The flaw in the argument advanced by Generic Defendants is obvious in the cases they cite in support of their position. They argue that the actions of the 5th and 8th Circuits in obeying the Supreme Court's directive that their decisions be reversed prove that they are correct. They further cite to two orders from federal district courts dismissing claims they allege are similar to those asserted by Plaintiffs in their TAMLFC, as an indication that everything has been said and done – but that is not the case. A closer reading of the orders cited in support of Generic Defendants' Preliminary Objections reveals that not a single one has addressed any of the arguments presented in July 18th, 2011 Position Statement from Plaintiffs' Liaison Counsel outlining the effect of *Mensing* on the claims asserted by Plaintiffs. Of the two district court orders dismissing plaintiff's claims, one acknowledges that the plaintiff had filed no response to defendants' motion to dismiss, and the other is the recommendation of a magistrate that all of plaintiff's claims be dismissed based on the "law of the case" doctrine. Generic Defendants can cite no authority that has analyzed the arguments advanced by Plaintiffs herein, and determined that all claims against a generic manufacturer are preempted by *Mensing.*

On the other hand, those courts that have actually considered the issues raised by Plaintiffs in their Position Statement, and which are discussed in this memorandum have

consistently determined that *Mensing* is not the last word. A Nevada state court determined that claims against a generic manufacturer for failing to send "dear doctor" letters are not preempted by *Mensing,* followed shortly thereafter by a similar order from a federal district court sitting in Alabama in a case involving metoclopramide. *Keck* Order, attached hereto as Exhibit E; *Brasley-Thrash* Order, attached hereto as Exhibit F. A federal court in South Carolina denied the a generic metoclopramide manufacturer's motion to dismiss based on arguments similar to those raised in Generic Defendants' Preliminary Objections, finding that generic manufacturers do indeed have a duty to communicate the warnings and information that appear in the approved labeling for their drugs to the medical community. *Fisher* Order, attached hereto as Exhibit D. While the *Fisher* court determined that certain of plaintiff's claims were preempted under *Mensing,* it found that plaintiff's claims for manufacturing defect, breach of implied warranties, fraud by concealment, negligence, negligence *per se,* unfair trade practices, intentional infliction of emotional distress, loss of consortium and punitive damages all survived the preemption decision in *Mensing.* Clearly, the courts that have considered the issue and the theories set forth in the Plaintiffs' Position Statement have determined that there remain viable causes of action against generic manufacturers.

In addition to misinterpreting the holding of the Supreme Court in *Mensing,* Generic Defendants' Preliminary Objections suffer from another fatal flaw. They do not cite to any provision of state law that they believe to be preempted. There can be no dispute that in order to determine if a state law is preempted, the law in question must first be identified. *See Mensing,* at 2573 ("Pre-emption analysis requires us to compare federal and state law"). Generic Defendants' failure to identify even a single provision of state law that conflicts with federal law is fatal to their argument. As Plaintiffs have not alleged that Generic Defendants were required

to change the labeling for their metoclopramide products to provide safer warnings, the only state-law requirement addressed by the Court in *Mensing*, Generic Defendants' preliminary objections must be denied in their entirety, for the reasons that follow.

II. MATTER BEFORE THE COURT

The Generic Defendants have file Preliminary Objections asserting that all of the claims alleged in Plaintiffs' Third Amended Complaint are preempted under the Supreme Court's decision in *PLIVA, Inc. v. Mensing.* The *Mensing* decision considered whether a generic manufacturer may be subjected to liability for failing to provide warnings in its label that were different than the warnings in the label of its brand-name equivalent. The court found that since generic manufacturers could not unilaterally change the contents of their labels, such claims were preempted. Nothing in *Mensing* insulates Generic Manufacturers from liability pursuant to state law duties that do not require them to change their labels. Since Plaintiffs' Complaint only asserts theories of liability that would not require Generic Defendants to alter the labels for their drugs, their Preliminary Objections should be denied because they are unaffected by *Mensing*.

III. STATEMENT OF QUESTION PRESENTED

Are Generic Defendants entitled to dismissal of claims asserted by Plaintiffs that do not allege that the information appearing in their labeling for metoclopramide should have been changed to differ from the label of the brand-name drug?

Suggested Answer: No.

IV. FACTS

At the time that each of Generic Defendants began manufacturing and selling metoclopramide, they were fully aware of the fact that the labeling for the drug lacked information necessary for the safe and effective use of the drug. Plaintiffs' TAMLFC at ¶¶ 102-

106, 108, 129. Not only did Generic Defendants know that the label lacked adequate instructions for use, they were also aware of the fact that their label contained false information which understated the risk of developing serious side effects by orders of magnitude. *Id.* They were also aware that the FDA had based approval of the drug on false and unscientific information, and that the drug was neither safe nor effective in treating those conditions for which it was being prescribed. *Id* at 88,89, 111,145.

Even further, Generic Defendants encouraged physicians and consumers to prescribe and ingest metoclopramide in a manner that was likely to result in severe injury. *Id* at ¶¶ 132-135. During the time that Generic Defendants were manufacturing and selling metoclopramide, they received further reports from qualified researchers that the label for metoclopramide vastly underestimated the dangers associated with use of the drug beyond 12 weeks, and that over one-third of the prescriptions being written for the drug were for periods longer than *one year*. *Id* at ¶¶ 102, 108. Fearing that the information would result in reduced sales, Generic Defendants concealed this information from the FDA, physicians and consumers, and represented and warranted instead that there was, in fact, no appreciable danger with metoclopramide use, and that use of the drug for periods longer than 12 weeks was entirely acceptable and safe, knowing that their failure to communicate important information was likely to result in severe injury to consumers. *Id* at ¶¶ 109, 119, 170, 171, 174, 201, 208, 225.

In 2004, when Schwarz Pharma, Inc., the Reference Listed Drug ("RLD") holder for metoclopramide changed the labeling for the drug to include a prohibition on long-term use, Generic Defendants were aware of the fact that the important new safety information had not been provided to physicians or consumers. *Id* at ¶¶ 118, 135,158, 159, 173, 174, 182, 201. Instead of alerting these individuals to the fact that therapy with the drug should not exceed 12

weeks in duration, Generic Defendants again concealed both its label and the new prohibition it contained from physicians and consumers. *Id.*

As set forth below, accepting these allegations as true, it is clear that Generic Defendants had numerous means at its disposal that could have prevented Plaintiffs' injuries, only one of which was to change the content of their labeling. As Plaintiffs have alleged that Generic Defendants sold metoclopramide with knowledge that the safety information contained within their label was false, that Generic Defendants were aware of the fact that physicians were prescribing and patients, including the Plaintiffs, were using their drug based on the false information and inadequate instructions that they provided (or failed to provide). Plaintiffs also appropriately allege that Generic Defendants concealed the fact that long-term use of metoclopramide was unlikely to be safe in spite of FDA-approved warnings indicating that use of the drug should not exceed 12 weeks in duration. Plaintiffs appropriately allege that the Generic Defendants' metoclopramide products were defective and not safe for their intended use. Clearly, Plaintiffs' Complaint identifies numerous theories of liability that were not considered, and therefore, not affected by the *Mensing* decision.

V. SUMMARY OF THE ARGUMENT

Generic Defendants argue that the U.S. Supreme Court's decision in *Mensing* mandates the dismissal of all of Plaintiff's claims. They ask the Court to find that since generic manufacturers cannot add new or different information to the labeling of their drug products, they are entitled to blanket immunity from liability for the serious harm they caused Plaintiffs' to suffer. Contrary to Generic Defendants' assertions, a review of the *Mensing* decision and the numerous allegations in Plaintiffs' Complaint show that the Court's decision affects only one

theory of liability that does not appear in Plaintiffs' TAMLFC, and that the numerous other theories advanced by Plaintiffs remain viable causes of action.

The preemption found to exist in *Mensing* bears only on one aspect of a drug label – its content. In order to be adequate, a manufacturer's warning must be judged not only by its content, but also by the manner in which it is communicated. In the present case, Generic Defendants never provided Plaintiffs or their physicians with ANY warning with regard to metoclopramide. Defendants' complete failure to provide physicians with any warning or instruction for proper use of their drug, warnings which were immensely important in light of changes made to the label for metoclopramide prohibiting long-term use, was an issue not before the *Mensing* Court, and the decision does not preclude claims based on such a theory.

Furthermore, the *Mensing* opinion clearly acknowledges that the Plaintiffs had not argued that a generic manufacturer could simultaneously comply with its duties under both state and federal law if it stopped selling its drug. Importantly, federal law prohibits the introduction into interstate commerce of any drug bearing a label that contains false or misleading statements, or that lacks adequate warnings or instructions for use. As noted by the United States in its Brief as *amicus curiae* in *Mensing*, whatever claims are supported by Plaintiffs' allegations under state law, are the equivalent of alleging that Generic Defendants' metoclopramide products were misbranded. As a result, any state law duty that requires manufacturers to stop selling their drugs while they are misbranded would not be preempted, as federal law requires precisely the same action.

In addition to its finding of preemption, the *Mensing* decision indicates that generic manufacturers *are* required to monitor the safety of their drug products once they enter the marketplace, and that federal law *requires* them to take certain action if and when they have

concerns regarding the safety of their drugs. Because Plaintiffs allege that Generic Defendants did not comply with their duty to monitor the safety of their drug, did nothing to identify or correct the problem they were creating of off-label use, claims based on violations of these duties (in addition to others) are not preempted.

Finally, *Mensing* did not consider the impact of additional warnings added to the label for metoclopramide in 2003 and 2004 regarding geriatric use and prohibiting use of the drug for longer than 12 weeks. As the labeling for metoclopramide last appeared in the *Physician's Desk Reference* (PDR) in 2002, these warnings were never communicated to the physicians who were prescribing metoclopramide or the individuals who were consuming it. *Mensing* presumed that the prescribing physician had been given the warnings appearing in the label of the name brand drug and did not consider Generic Defendants' duty to inform physicians and consumers of information and warnings appearing in the FDA approved labeling for the drug, yet not published in the PDR. In addition to their numerous other failures, Generic Defendants failed entirely to alert Plaintiffs or their physicians to the existence of these warnings at any time.

VI. LAW AND ARGUMENT

For purposes of reviewing preliminary objections based upon legal insufficiency, all well pleaded material, factual averments and all inferences fairly deducible therefrom are presumed to be true. *Baker v. Brennan*, 419 Pa. 222, 225, 213 A.2d 362, 364 (1965). When presented with preliminary objections whose end result would be the dismissal of a cause of action, a court should sustain the objections where it is clear and free from doubt from all the facts pleaded that the pleader will be unable to prove facts legally sufficient to establish its right to relief. *Id.*

A. THE *MENSING* DECISION

Generic Defendants' Preliminary Objections mistakenly argue that the claims before the Court in *Mensing* are indistinguishable from those alleged by Plaintiffs in the present case. It is abundantly clear from the Court's ruling in *Mensing* that the issue it decided was a narrow one – whether a state law requirement that a generic drug manufacturer change the contents of its label was preempted by the federal requirement that generic labeling match that of the Reference Listed Drug ("RLD"). The Court made clear that it was making no determination of what state law required of a manufacturer, but rather acknowledged that "the parties [did] not dispute" that the laws of Louisiana and Minnesota required a generic manufacturer to change their label to meet the duties imposed by state law. *Mensing*, 131 S.Ct at 2574. While *Mensing* affects one theory of liability that may be asserted against a generic drug manufacturer, it is by no means dispositive of all of Plaintiffs' claims.

The United States Supreme Court has consistently and repeatedly rejected an approach to preemption such proposed by Generic Defendants - that all causes of action are preempted by federal law simply because particular claims are preempted.[4] As discussed below, the Court's decision in *Cipollone v. Liggett Group, Inc.* rejected the notion that the descriptive label attached to a particular claim determines whether it is preempted. 505 U.S. 504, 521 (1992). In resolving preemption issues, a Court must undertake a preemption analysis whereby it scrutinizes the duty imposed by each of a plaintiff's state law claims before it determines which are preempted. *Id; see also Spain v. Brown and Williamson Tobacco Corp.*, 363 F.3d 1183, 1193 (11th Cir. 2004); *Wright v. Brooke Group Ltd.*, 114 F. Supp. 2d 797, 824 (N.D. Iowa 2000); *LaBelle v. Brown &*

[4] *See, e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (plaintiff's failure to warn claims imposing requirements "different or in addition to" those required by federal law were preempted, whereas plaintiff's negligent failure to warn, express warranty, fraud, misrepresentation, and conspiracy claims survived); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005) (remanding plaintiff's failure to warn and fraud claims to determine conflict with state law, but finding no preemption with regard to plaintiff's defective design, defective manufacture, negligent testing, breach of express warranty, or violation of consumer protection statute claims); *Altria Group Inc., v. Good*, 555 U.S. 70 (2008) (affirming *Cipollone*, and finding claims based on violation of state's unfair trade practice statute not preempted).

Williamson Tobacco Corp., 2:98-3235-23, 1999 WL 33591435 (D.S.C. 1999). In *Mensing*, the Court found there to be "impossibility preemption" – that it would have been impossible for a generic manufacturer to comply with both state and federal law. Whether specific state law claims will be preempted thus depends on whether there is an "actual conflict" between the requirements of the state and the federal government. *See e.g. English v. General Electric Co.*, 496 U.S. 72, 79 (1990); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143.

Generic Defendants' argue that cases involving express preemption clauses are inapplicable to the present case. While they may wish that this were true, as this is where the majority of the authority on the topic is found, it is certainly not the case. The only difference between the analysis performed in an express preemption case and an implied preemption case, is that a court must first determine the scope of the preemptive federal law in a case involving an express preemption clause. The scope of the preemptive statute bears only on the federal law involved in a preemption analysis – and there is no dispute as to the scope of the preemption announced in *Mensing*. The court found that the federal requirement that a generic drug's labeling match that of the brand name drug preempts a state law that requires a generic manufacturer to change the content of its labeling. The "same as" requirement appears in 21 U.S.C. §355(j)(2)(A), and applies to the active ingredients, dosage form, route of administration and labeling for a generic drug. The preemption announced in *Mensing* is confined to this single statutory subsection. Furthermore, the analysis of the state law claims at issue does not differ at all in the context of either express or implied preemption, as the comparison is the same in either case. Thus, where the Supreme Court discusses the requirements and duties imposed by state law, it makes no difference whether the statements are made in the context of express or implied

preemption. The type of preemption has no bearing on the determination of the duty imposed on a manufacturer by a common-law damage action.

In order to perform a preemption analysis on the claims asserted by Plaintiffs, one must first determine what federal law requires, what is required under state law, and the extent to which those requirements conflict. The Court in *Mensing* stated the issue before the Court as follows:

> To summarize, the relevant state and federal requirements are these: State tort law places a duty directly on all drug manufacturers to adequately and safely label their products. Taking Mensing and Demahy's allegations as true***, this duty required the manufacturers to use a different, stronger label than the label they actually used***. Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels. But, we assume, federal law also required the Manufacturers to ask for assistance in convincing the brand-name manufacturer to adopt a stronger label, so that all corresponding generic drug manufacturers could do so as well.

Mensing, 131 S. Ct. at 2577 (emphasis added).[5] Thus, the finding of preemption in *Mensing* is premised upon a state law which would require a manufacturer to actually the change the content of its label. The Court based its finding of preemption on the fact that state law would have required defendants to provide different, additional warnings than appeared in the labeling for the reference listed drug ("RLD"), and that it was impossible to do so under federal law, as a generic drug's label is required to be the same as the RLD. When considered in the context of other Supreme Court precedent, including the Court's finding in *Wyeth v. Levine*, 555 U.S. 555 (2009), that there are no broader preemption principles at issue, it is clear that the narrow legal situation described in *Mensing* (where a state's law requires the specific action of changing the content of the label for a prescription drug) is irrelevant to all of the theories of liability presented in Plaintiffs' Complaint.

[5] The *Mensing* Court also noted that the parties did not dispute that the only law at issue was a state law that "required the Manufacturers to use a different, safer label." *Id* at 2574.

In addition to its finding of preemption as described above, the *Mensing* Court also acknowledged that generic manufacturers have a duty to keep abreast of information regarding their drug's effect on consumers in the marketplace, and that they must take action (notifying the FDA and/or brand-name manufacturer) when there is evidence that its drug may be harming people. While *Mensing* was pending before the Supreme Court, the United States stated its official position on the interpretation of applicable regulations in an *amicus curiae* brief filed at the request of the Court. 2011 WL 741927 (U.S. 3/2/2011). The Court based its decision in *Mensing* on the fact that the FDA indicated in its brief that generic manufacturers were not allowed to unilaterally change the contents of their package inserts to provide different or additional warnings.

That is not all that the FDA's brief stated, however - it also stated that generic manufacturers DO have a duty to monitor the safety of their drugs in the medical and scientific literature, to review the labeling for their drug products to determine if it is adequate and accurate, and to inform the FDA of labeling deficiencies so that the agency might take appropriate action. Specifically, the agency stated the following:

> Information on the risks and benefits associated with a drug may accumulate over time. Accordingly, NDA and ANDA holders must keep records of clinical experiences and ensure that their drugs remain safe and effective as labeled. In particular, implementing regulations provide that a manufacturer must record and report certain adverse events to FDA, and must also annually report a summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product and a description of actions the applicant has taken or intends to take as a result of that new information.

Id at pg. 6 (internal citations omitted). The FDA characterized the actions required of a generic manufacturer as follows:

> FDA regulations require NDA holders and ANDA holders alike to act upon new safety information that warrants added or strengthened warnings. Petitioners are correct that, in meeting that federal duty, they could not properly have invoked the CBE or PAS process,

> or sent the sort of DHCP letter respondents envision. But ANDA holders nonetheless should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.

Id at pg. 12. Plaintiffs have alleged that Generic Defendants did NOTHING to comply with these obligations.

Generic Defendants' Preliminary Objections argue that even though they failed entirely to meet duties imposed upon them by both state and federal law, they should be exempt from all liability because they could not have unilaterally changed the contents of their label. A reading of Plaintiffs' TAMLFC makes it clear that Plaintiffs have not alleged that Generic Defendants failed to change the content of their label, but that their label contained false information, that Generic Defendants failed to *communicate* existing warnings to the medical community, and that Defendants "failed to use reasonable care" in *providing* warnings, in addition to other allegations. There is simply no support for Defendant's proposition that all such claims are preempted under *Mensing*. To the contrary, *Mensing* states that federal law requires the label for a generic drug to be the same as the RLD, so that any claim brought by a Plaintiff which is based on a generic manufacturer's failure to change the content of their label (one type of "failure-to-warn" claim) would be preempted. *Mensing* says absolutely nothing about a manufacturer's duty to *provide* a warning (i.e. communicate information appearing in FDA-approved labeling to physicians or consumers), to *discover and report* the risks associated with its product, nor does it speak to the other causes of action asserted by Plaintiffs.

B. PREEMPTION AND FEDERAL LABELING REQUIREMENTS

As the Court's decision in *Mensing* dealt only with claims based on the alleged deficiency of the contents of the labeling for a generic drug, the decision must be read in conjunction with other pronouncements the Court has made with regard to preemption of claims

based on a product's labeling. The guidance offered by these cases clearly shows that the claims asserted by Plaintiffs in their TAMLFC remain intact when considered in light of *Mensing.*

While a specific statute or regulation may be found to preempt certain state laws, such a finding says nothing about the *scope* of that preemption. *Bates,* 544 U.S. at 433-434. In cases where express pre-emption is at issue, the scope of the preemption is determined by the language of the statute. *Cipollone,* 505 U.S. at 516; *Bates,* 544 U.S. at 433-434. In cases of conflict preemption, a state's laws are preempted only to the extent such law conflicts with the federal law. *See Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 884 (2000). With regard to impossibility preemption, which the Court found to exist in *Mensing,* and which Generic Defendants argue applies to the claims at issue here, state law is preempted only to the extent that it is "impossible for a private party to comply with both state and federal requirements." *Mensing,* 131 S.Ct. at 2577, quoting *Freightliner Corp. v. Myrick,* 514 U.S. 280, 287 (1995). In determining any pre-emption issue, a court is to be guided by the "two cornerstones" of pre-emption jurisprudence:

> First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." Second, "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated ... in a field which the States have traditionally occupied,' ... we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' "

Wyeth v. Levine, 555 U.S. 555 (2009) (internal citations omitted).

The Supreme Court has recognized that while the common law does not normally require a vendor to use any specific statement on its packages or advertisements, it does serve to enforce duties that constitute either "affirmative *requirements*" or "negative *prohibitions*" contained in those laws. *Cipollone,* 505 U.S. at 522 (emphasis in original). A "requirement" such as considered by the *Mensing* Court, is a rule of law that must be obeyed; an occurrence that merely

motivates an optional decision by a manufacturer (such as the rendering of a jury verdict) does not qualify as a requirement. *Bates,* 544 U.S. at 444.

Furthermore, where a state law "prohibition" restricts activities that are only *permitted* by the federal government, and not *required,* no conflict exists. *See Florida Lime & Avocado Growers, Inc., v. Paul,* 373 U.S. 132, 144-145, citing *Cloverleaf Butter Co. v. Patterson,* 315 U.S. 148 ("a State might nevertheless – at least in the absence of an express contrary command of Congress – confiscate or exclude from market the processed butter which had complied with all federal processing standards, 'because of a higher standard demanded by a state for its consumers.'"); *see also Barnett Bank v. Nelson,* 517 U.S. 25 (1996) (finding no impossibility preemption to exist where a federal statute permitted national banks to sell insurance in small towns, but a state statute prohibited the same activity). As stated by the Court, "Congressional regulation of one end of the stream of commerce does not, ipso facto, oust all state regulation at the other end." *Florida Lime & Avocado Growers, Inc.,* 373 U.S. at 1219. As a result, if the Generic Defendants could have complied with any of their duties under state law by taking actions other than changing the content of its label (such as refraining from putting its metoclopramide on the market, which neither federal nor state law required it to do), a claim based on such law would not be preempted.

1. *Cipollone v. Liggett Group, Inc.*[6] and *Altria Group, Inc. v. Good*[7]

The first instance in which the Supreme Court had the opportunity to consider the preemptive effect of state law claims as they specifically relate to federally regulated labeling was in *Cipollone v. Liggett Group, Inc.* The federal statute at issue in *Cipollone* was the Federal Cigarette Labeling and Advertising Act, as amended by the Public Health Cigarette Smoking Act

[6] 505 U.S. 504 (1992)
[7] 555 U.S. 70 (2008)

of 1969. *Id* at 510. There was an express preemption provision in the federal law which provided that "[n]o statement relating to smoking and health, other than the statement required by [federal law] shall be required on any cigarette package." *Id* at 514. In addition to the prohibition on any requirements for statements appearing on the packages themselves, federal law also preempted states from including different or additional statements in the advertising or promotion of cigarettes, which were also considered labeling. *Id.*

In a plurality opinion, the Supreme Court divided the claims asserted by the plaintiff into five categories (1) design defect claims, (2) failure to warn claims, (3) negligence claims (including negligent failure to warn)[8], (4) express warranty claims, and (5) fraudulent misrepresentation claims. *Id* at 511. The District Court had found all except the design defect claims to be preempted. *Id* at 512. Before analyzing each of these categories, the Court began by acknowledging the fact that federal law requires a particular warning label for a product "does not by its own effect foreclose additional obligations imposed under state law" and that "there is no general, inherent conflict between federal preemption of state warning requirements and the continued validity of state common-law damages actions." *Id* at 518. The Court then undertook to analyze each of the asserted claims in order to determine whether they were preempted.

With regard to Plaintiff's failure-to-warn claims, the Court separated the claims that alleged that defendants "failed to provide 'adequate warnings of the health consequences of cigarette smoking'" from those alleging that defendants "were negligent in the manner [that] they tested, researched, sold, promoted, and advertised their cigarettes." *Id* at 525. With respect to Plaintiff's failure-to-warn claims, the Court found:

> Thus, insofar as claims under either failure to warn theory require a showing that respondents' post-1969 advertising or promotions should have included additional, or

[8] Notably, the plaintiff in *Cipollone* referred only to "failure to warn" claims. In its analysis, the Court separated certain of these claims from others, finding that while some were preempted by the federal law, others were not.

> more clearly stated, warnings, those claims are pre-empted. The Act does not, however, pre-empt petitioner's claims that rely solely on respondents' testing or research practices or other practices unrelated to advertising or promotion.

Id.

Next, the Court determined that Plaintiff's breach of express warranty provisions were not preempted by federal law. In finding no preemption, the Court rejected the finding of the District Court that since the warranty at issue consisted solely of statements appearing in defendant's advertising, that the breach of warranty claim would "inevitably bring into question [respondents'] advertising and promotional activities," and that the claim was therefore preempted. *Id* at 525. The Court stated that the proper inquiry "is not whether a claim challenges the 'propriety' of advertising and promotion, but whether the claim would require the imposition under state law of a requirement or prohibition based on smoking and health." *Id.* The Court went on to state as follows:

> A manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the 'requirement[s]' imposed by an express warranty claim are not "imposed under state law," but rather imposed *by the warrantor*… In short, a common-law remedy for a contractual commitment voluntarily undertaken should not be regarded as a "requirement… imposed under State law" within the meaning of [the Act].
>
> That the terms of the warranty have been set forth in advertisements rather than in separate documents is irrelevant to the pre-emption issue… because, although the breach of warranty claim is made "with respect … to advertising," it does not rest on a duty imposed under state law. Accordingly, to the extent that petitioner has a viable claim for breach of express warranties made by respondents, that claim is not preempted by the 1969 Act.

With regard to the fraudulent misrepresentation claims advanced by the plaintiff, the Court found those claims to be preempted to the extent plaintiff were alleging that these statements "negate or disclaim" the warnings required under federal law. *Id* at 527-528. The Court also determined, however, that Plaintiff's misrepresentation claims alleging that

defendants made false representations of material fact and/or concealed material facts were not preempted:

> Petitioner's claims that respondents concealed material facts are therefore not pre-empted insofar as those claims rely on a state-law duty to disclose such facts through channels of communication other than advertising or promotion. Thus, for example, if state law obliged respondents to disclose material facts about smoking and health to an administrative agency, § 5(b) would not pre-empt a state-law claim based on a failure to fulfill that obligation.
> …
> State-law prohibitions on false statements of material fact do not create "diverse, nonuniform, and confusing" standards. Unlike state-law obligations concerning the warning necessary to render a product "reasonably safe," state-law proscriptions on intentional fraud rely only on a single, uniform standard: falsity.

Id at 528-29. The Court then found that Plaintiff's conspiracy claims were not preempted for the same reasons that it did not find their fraudulent misrepresentation claims to be preempted.

As stated above, the analysis employed by the Court in *Cipollone* was only subscribed to by a plurality of the justices. In 2008, however, the Court issued another decision with regard to the same federal law at issue in *Cipollone.* In *Altria Group, Inc. v. Good* a majority of the Court rejected the argument advanced by defendants that plaintiff's claims of fraud and violation of a state's Unfair Trade Practices Act were disguised failure-to-warn claims. *Altria*, 555 U.S. at 545-546 ("To be sure, the presence of the federally mandated warnings may bear on the materiality of petitioners' allegedly fraudulent statements, 'but that possibility does not change respondents' case from one about the statements into one about the warnings"). In doing so, the Court adopted the analysis employed by the plurality in *Cipollone.*

2. *Bates v. Dow Agrosciences LLC*[9]

In the time between the *Cipollone* and *Altria* decisions discussed above, the Supreme Court rendered another decision involving preemption in the context of federal labeling

[9] 544 U.S. 431 (2005).

requirements. In *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005), the statute at issue was the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Farmers in Texas brought numerous state law causes of action against Dow Agrosciences for damage caused by a pesticide which had been labeled in compliance with federal law. *Id.* Much the same as the FDCA provisions at issue in *Mensing*, FIFRA contained an express preemption clause which preempted any claims brought under state law which would "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required" by federal law. *Id* at 442.

Adhering to the analytical framework announced in *Cipollone* and *Altria*, the Supreme Court rejected the defendant's argument that a jury verdict brought under any cause of action would be preempted because a successful claim would "induce" a manufacturer to change its label, thereby achieving the same end as a failure-to-warn claim. *Id* at 443. The Court stated:

> For a particular state rule to be pre-empted, it must satisfy two conditions. First, it must be a requirement "*for labeling or packaging*"*;* rules governing the design of a product, for example, are not pre-empted. Second, it must impose a labeling or packaging requirement that is "*in addition to or different from* those required under this subchapter." A state regulation requiring the word "poison" to appear in red letters, for instance, would not be pre-empted if an EPA regulation imposed the same requirement.

Id at 444. The court went on to announce that it was "perfectly clear" that many of the common law rules which served as the basis for Plaintiff's claims did not satisfy the first condition. In the words of the Court:

> Rules that require manufacturers to design reasonably safe products, to use due care in conducting appropriate testing of their products, to market products free of manufacturing defects, and to honor their express warranties or other contractual commitments plainly do not qualify as requirements for "labeling or packaging." None of these common-law rules requires that manufacturers label or package their products in any particular way. Thus, petitioners' claims for defective design, defective manufacture, negligent testing, and breach of express warranty are not pre-empted.

Id.

The Court went on to acknowledge that the express warranties identified by the Plaintiff were located in the text of the label for Dow's product, which could not be altered without the approval of the EPA, and that failure-to-warn claims based on the adequacy of such labeling would be pre-empted. The Court found however, that a cause of action for breach of an express warranty requires only "that a manufacturer make good on the contractual commitment that it voluntarily undertook by placing the warranty on its product." *Id.* The Court found that because the common-law rule did not require the manufacturer to make the express warranty (i.e., to sell the product), and the fact that the common-law rule did not require any specific warranties to be made, that it was not preempted under FIFRA. *Id.*

With regard to Dow's argument that a finding of liability on any of those claims would "induce Dow to alter [its] label," the Court stated the following:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue, see *Cipollone*, 505 U.S., at 524, 112 S.Ct. 2608 (plurality opinion); it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants).

Bates, 544 U.S. at 445.

The *Bates* Court also reaffirmed the availability of so-called "parallel claims" – causes of action brought under provisions of state law that enforce requirements imposed by federal law:

> Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA. Unlike the cigarette labeling law at issue in *Cipollone*, which prescribed certain immutable warning statements, FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings. As one court explained, tort suits can serve as a catalyst in this process:
>
> By encouraging plaintiffs to bring suit for injuries not previously recognized as traceable to pesticides such as [the pesticide at issue], a state tort action of the kind under review may aid in the exposure of new dangers associated with pesticides. Successful actions of

> this sort may lead manufacturers to petition EPA to allow more detailed labeling of their products; alternatively, EPA itself may decide that revised labels are required in light of the new information that has been brought to its attention through common law suits. In addition, the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.

Id at 451, *quoting Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1541-1542 (C.A.D.C. 1984). The Supreme Court has stated that the same justification exists for allowing tort claims to proceed against pharmaceutical manufacturers. *See Wyeth v. Levine*, 555 U.S. 555 (2009)[10].

The *Cipollone*, *Bates* and *Altria* cases make it clear that *Mensing* only serves to preempt certain state law actions based on a theory that would require the defendant to change the content of their label to differ from that of the RLD. All other causes of action remain unaffected. Furthermore, any claims that do not require Plaintiffs to show that the generic manufacturers were required to provide a warning with content that differed from the labeling of the RLD would not be preempted for the reasons stated above.

C. OTHER FEDERAL LAW REQUIREMENTS

1. The FDCA and Misbranding

As the Supreme Court has acknowledged, since its inception, the FDCA has "prohibited the manufacture or interstate shipment of adulterated or misbranded drugs" and "supplement[s] the protection of consumers already provided by state regulation and common-law liability." *Wyeth v. Levine*, 129 S.Ct. at 1195-1196 (2009). As noted by the United States in its *amicus* brief, "a drug is 'misbranded' in violation of the FDCA when its labeling is false or misleading,

[10] "The FDA has limited resources to monitor the 11,000 drugs on the market and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. 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."

or does not provide adequate directions for use and adequate warnings." 2011 WL 741927 at *3 (internal citations omitted). Under the FDCA, a manufacturer may not introduce into commerce a misbranded drug. 21 U.S.C. 331(a).[11] In addition to prohibiting manufacturers from selling or distributing a misbranded drug into interstate commerce, the FDCA also requires a generic manufacturer to take action when it believes its labeling is inadequate or inaccurate. *Id* at *26, ("… federal law requires a manufacturer to act to update its labeling..."). The *amicus* brief also found that allegations such as Plaintiffs', that a generic manufacturers' drug labeling understated the risks associated with a drug and lacked adequate directions for use, were the equivalent of alleging the drug was misbranded :

> In addition to whatever claim those allegations state under state law, they would also establish that petitioners' metoclopramide products were misbranded under 21 U.S.C. 352(f)(2) because those drugs would lack adequate warnings, and petitioners would have failed to discharge their duty under Section 201.57(e) to seek a revision to their approved labeling in light of newly acquired information not previously considered by FDA.

Id at *30.

Neither the Brief for the United States as *amicus curiae, n*or the Court's decision in *Mensing* addressed the ability of a Plaintiff to assert liability against a generic drug manufacturer for continuing to manufacture and distribute its drug, despite the fact that it is misbranded. In fact, both the Solicitor General's brief, and the *Mensing* opinion acknowledged that Plaintiff had not advanced such an argument.[12] *Id* at 25; *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2588

[11] The FDCA describes the acts it prohibits to include"[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."

[12] "Drugs with FDA approval are presumptively lawful to sell in commerce. Respondents do not contend otherwise or suggest that petitioners' drugs simply should not have been available on the market." *Amicus* brief at pg. 25; "In its decision below, the Eighth Circuit suggested that the Manufacturers could not show impossibility because federal law merely permitted them to sell generic drugs; it did not require them to do so. See *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product"); see also *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000) (describing "a case of impossibility" as one "in which state law penalizes what federal law *requires* "

(2011). As a result, it cannot be said that this theory of liability is precluded by the Court's decision.

2. Communication of Drug Safety Information

In 1996, Congress joined FDA in recognizing problems regarding the ineffective communication of important information regarding prescription drug products, and directed the pharmaceutical industry and other stakeholders to develop a long-range comprehensive action plan to achieve goals consistent with FDA's proposed rule.[13] The FDA has consistently reinforced this policy of achieving effective communication of prescription drug information.[14] In providing guidance regarding the dissemination of information to the public, FDA has, for example, suggested that "sponsors also use various methods to communicate drug safety information." For example, a sponsor may distribute a 'Dear Health Care Professional' letter (sometimes referred to as a "Dear Doctor" letter) to convey important information regarding a marketed drug. ***A sponsor may issue a Dear Healthcare Professional letter on its own initiative*** or following a request by the FDA."[15] The FDA explained that "Dear Healthcare Professional

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(emphasis added)). Respondents have not advanced this argument, and I find it unnecessary to consider." *Mensing*, 131 S.Ct. at 2588.

[13] *See* Pub. L. 104-180. In response to Congress' directive, a committee including representatives of the pharmaceutical industry submitted a plan to the Secretary of the Department of Health and Human Services in December, 1996. *See* Action Plan for the Provision of Useful Prescription Medicine Information, *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/Reports Budgets/UCM163793.pdf.

[14] *See, e.g.*, Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion (2009), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/ Guidances/ UCM155480.pdf.

[15] Guidance: Drug Safety Information – FDA's Communication to the Public (2007), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/_____ (emphasis supplied, internal citations omitted).

While *Mensing* determined that a generic manufacturer could not send "Dear Doctor Letters" that contained different or additional warnings, the Court did not consider whether a generic manufacturer could send such a letter to alert of recent FDA-approved changes, such as the prohibition on long-term use added to the Reglan label in 2004, which the Solicitor General's *amicus* brief indicated would be appropriate. *See also Keck v. Endoscopy Center of Southern Nevada*, Case No. A57837, Order dated 8/19/2011, attached as Exhibit A (finding that claims

letters may be used to disseminate information regarding a significant hazard to health, ***to announce important changes in product labeling***, or to emphasize corrections to prescription drug advertising or labeling." *Id*. (emphasis supplied).

Clearly, generic drug manufacturers' disseminating **NO INFORMATION AT ALL** regarding metoclopramide to either prescribers or patients is contrary to federal policy and guidelines. Generic drug manufacturers not only could and should have widely ***disseminated*** the information contained in updated, FDA-approved labeling, but according to related FDA guidelines, they ***independently*** could and should have done much more. FDA has indicated that the process of risk minimization should be continually performed by a manufacturer as long as their drug is on the market.[16] FDA also advises manufacturers that they should consider input from health care professionals and consumers when assessing risk and when considering taking actions designed to minimize this risk. *Id.*

In providing guidance, FDA has identified numerous means of communication all drug manufacturers can and should take to minimize an identified risk ***besides a change in labeling***.[17] FDA points to the lack of effectiveness of labeling changes alone to address identified risks as one rationale for advocating the use of these tools.[18] Some of the means that have been long available to a generic manufacturer to minimize an identified risk are: (1) training programs for healthcare practitioners or patients; (2) continuing education for healthcare practitioners; (3)

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that a generic manufacturer should have sent "Dear Doctor Letters" that were "consistent and not contrary to" FDA-approved labeling were not preempted under *Mensing*); *Brasley-Thrash v. Teva Pharmaceuticals USA, Inc.*, CA No. 10-00031 (S.D. Ala), Order dated 9/12/11, attached as Exhibit B (same).

[16] Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (2005), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf.

[17] Guidance for Industry: Development and Use of Risk Minimization Action Plans (2005) ("RiskMAP Guidance"), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071616.pdf.

[18] *Id*. at 12-13.

prominent professional or public notifications; (4) promotional techniques such as direct-to-consumer advertising highlighting appropriate patient use or product risks; (5) patient-sponsor interaction and education systems such as disease management and patient access programs; and (6) specialized packaging to enhance safe use of the product. *Id; see also, id* at 6, n. 7.

Federal policy is, therefore, clear and unequivocal – manufacturers must ensure that information regarding the safety and efficacy of prescription drugs reaches those who prescribe, dispense and ingest these drugs. *Mensing* does not address or bar claims where a drug manufacturer has provided inadequate notice of information already appearing in FDA-approved labeling. Nor does it preempt any claim where the manufacturer could have satisfied its duty under state law by approaching the FDA with information supporting a label change for metoclopramide, or by suspending sales of its drug. Instead, it addresses only those claims involving a generic manufacturer's duty to change the *content* of the drug's labeling.

Furthermore, no Defendant took any steps to communicate the information in the FDA-approved label for metoclopramide to the medical community after 2002, the last time product information for the drug appeared in the *Physicians' Desk Reference*. This included certain Generic Defendants failure to even include the additional warnings in their metoclopramide label for 5 years or longer. The result was a complete failure to alert the proper parties that the warning for metoclopramide had been strengthened in 2004 to prohibit exposure to the drug longer than 12 weeks in duration. Where a plaintiff's labeling claims rest on an assertion that a defendant negligently failed to comply with duties equal to, or substantially identical to, requirements imposed under federal law, preemption does not preclude such claims. *See Medtronic v. Lohr,* 518 U.S. 470, 496 (1996).

D. GENERIC DEFENDANTS' ARGUMENTS

In each of the arguments advanced by Generic Defendants' they confuse terminology and confuse issues. Prior to addressing each of their arguments, it is necessary to clarify the confusion apparent in Generic Defendants' argument. Initially, Generic Defendants Objections use the terms "label" and "warning" interchangeably. These terms are different and distinct, and are not equivalent. Whether a product's label serves as a warning is a question for a jury to decide. *Borel v. Fibreboard Paper Products Corp.*, 493 F.2d 1076 (5th Cir. 1973). Generic Defendants also use the terms "inaccurate" and "inadequate" interchangeably which is inappropriate. To be sure, Generic Defendants' metoclopramide were both inaccurate and inadequate, but for different reasons.

Inaccurate is the equivalent of false - therefore the statement underestimating the risk of developing a movement disorder from metoclopramide use by a factor of 100 or more, along with the statement that the risk of movement disorders was "rare" are inaccurate and false. Inadequate is a subjective determination. Thus, a product's labeling may be adequate and also inaccurate if it contains false information, but still serves to alert the user to dangers posed by a product. At all times Plaintiffs have alleged that the warnings provided by defendants were inadequate to alert a user to the dangers of long-term metoclopramide use. While the inadequacy of the warning may have been due in part to the inaccurate and false underestimation of the risks of the drug, that does not mean the warning could not be rendered adequate by drawing proper attention to the dangerous use.

Precisely on point is to label change forced upon the Generic Defendants by the FDA in 2009. This change includes a black box warning regarding the risk of tardive dyskinesia associated with long-term use of metoclopramide. While the metoclopramide label is still

inaccurate, as it contains false information that underestimates the risks accompanying metoclopramide use, the warning against long-term use has likely been rendered adequate. This is because the FDA made a prominent change that it brought to the attention of users and prescribers which directly addressed long term use. These actions serve to negate any effect that the underestimation of risk may have on the warning. Notably, the FDCA prohibits the introduction into interstate commerce of drugs bearing labels that contain false information, and drugs whose labels lack adequate directions for use, so while the label for metoclopramide may no longer be "misbranded" for lacking an adequate warning or instructions for use, it would still be misbranded because it contains false information. While similar, these terms have distinct meaning and cannot be used interchangeably, as Generic Defendants do in their Objections.

1. **Generic Defendants Could Have Unilaterally Sent "Dear Doctor" Letters That Were Consistent With, and not Contrary to Approved Labeling**

Generic Defendants' Objections spend a great deal of time arguing an issue which is not in dispute – a generic manufacturer cannot send warnings that are different or in addition to those that appear in the approved labeling for the drug. Hidden amidst these arguments, however, is the incorrect proposition that generic manufacturers cannot send "Dear Doctor" letters to alert physicians about important safety information, such as labeling changes. Every citation made by defendant that states a generic manufacturer may not unilaterally send such letters was made in reference to a letter that contained information that is different or in addition to the approved labeling for a drug. A reading of the Brief of the United States as *amicus curiae* shows clearly that claims that Generic Defendants could have alerted physicians to important safety-related labeling changes such as the information regarding use of metoclopramide in geriatric patients that was added in 2003, and prohibition on long-term use added in 2004 through use of a "Dear Doctor" letter.

As stated in the United States' *amicus* brief:

> To be sure, nothing in the FDCA or FDA's regulations categorically forbids an ANDA holder from unilaterally sending a DHCP letter. And a DHCP letter can be an appropriate way to bring new information to the attention of medical professionals. But the particular letter respondents envision [providing information not in the approved labeling] would only be appropriate in tandem with a corresponding change to the drug's approved labeling.

at pg. 18.

Given the above, it is clear the Generic Defendants could have alerted physicians to the 2003 and 2004 labeling changes for metoclopramide. In fact, since *Mensing* was decided, courts have decided exactly that. The Nevada District Court for Clark County found that *Mensing* did not preempt a plaintiff's claim that a generic should have informed physicians about information appearing in the approved labeling for their drug, as did a federal district court sitting in Alabama. *Keck* Order, Ex. E; *Brasley-Thrash* Order, Ex. F. The court in *Fisher v. Pelstring, et al.* determined that the generic metoclopramide manufacturer had "avenues available to it to communicate with physicians about the 2003 and 2004 label changes without seeking FDA approval first." *Fisher* Order, Ex. D. The avenue identified by the court was a "Dear Doctor" letter alerting them of the change. Generic Defendants' argument in this regard is unsupported and unpersuasive.

2. Plaintiffs' Claims Against Generic Manufacturers Are Not Preempted Under *Buckman v. Plaintiffs' Legal Committee*

Generic Defendants' arguments that their failure to include important safety information that appeared in the approved labeling for their drug ignores the fact that preemption does not serve to preclude "parallel" – state law claims whose requirements are the same as those imposed by the federal government, such as Plaintiffs' claims for negligence *per se*. As stated by the U.S. Supreme Court in *Medtronic v. Lohr*,

> Nothing in [the federal statute] denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of [state] law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

518 U.S. 470, 495 (1996); *see also Riegel v. Medtronic,* 552 U.S. 312, 330 (2008) (stating that federal law "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).

Generic Defendants ignore this fundamental aspect of preemption jurisprudence, opting instead to cite to the decision of the U.S. Supreme Court in *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001). They assert that their failure to comply with federal requirements is immaterial, as any claim taking their violation of FDA regulations into account would be preempted because "plaintiff does not have standing to enforce violations of the FDCA." Generic defendants misunderstand *Buckman,* and Plaintiffs' allegations. The issue before the Court in *Buckman* was whether an individual who owed no traditional state law duty to a plaintiff could assert liability for fraudulent representations made by that party to the FDA.[19] The Court distinguished the fraud-on-the-FDA claims asserted in *Buckman* from "traditional state tort law principles of the duty of care" owed by the manufacturer of a product, finding that the latter claim did not rise "solely from the violation of FDCA requirements." 531 U.S. at 352.

[19] The defendant in *Buckman* was not the manufacturer of the product that had caused the plaintiffs' injuries, but was rather a third party consultant whom the manufacturer had retained to negotiate the FDA approval process for their medical device. *Buckman,* 531 U.S. at 344.

The Court stated that although "certain state-law causes of action that parallel federal safety requirements" would not be preempted, it could not be said that "*any* violation of the FDCA will support a state-law claim." *Id.*

In the present case, Plaintiffs are not alleging any "freestanding" causes of action, but rather only traditional state law tort causes of action. Numerous courts have refused to accept the theory advanced by Generic Defendants, finding that claims based on a violation of FDA regulations are not preempted under *Buckman.* The 8th Circuit rejected the argument advanced by Generic Defendants finding that "the present case is distinguishable from *Buckman* because Lefaivre's state-law claims are not fraud-on-the-FDA claims, as they 'focus on [harm] that is allegedly perpetrated against [consumers] rather than the FDA.'" *Lefaivre v. KV Pharm. Co.,* 636 F.3d 935, 944 (8th Cir. 2011), citing *Couick v. Wyeth, Inc.,* No. 3:09–cv–210–RJC–DSC, 2009 WL 4644394, at *5 (W.D.N.C. Dec. 7, 2009) (unpublished) (metoclopramide case holding that *Buckman* did not apply to plaintiff's state-law claims, including claims for unfair trade practices and breach of warranties); see also *Fulgenzi v. Wyeth, Inc.,* 686 F.Supp.2d 715, 724 (N.D.Ohio 2010) (holding that Buckman did not apply to plaintiff's "multiple state law tort claims, including several claims sounding in fraud"). "The misrepresentation at issue in Buckman was not made to the plaintiff—or consumers at large—but to the FDA itself." *In re Bayer Corp. Combination Aspirin Prod. Mktg. & Sales Practices Litig.,* 701 F.Supp.2d 356, 369 (E.D.N.Y.2010). As stated in response to the same argument advanced by a generic defendant in a case involving metoclopramide, "simply because conduct violates the FDCA does not mean a state-law claim based on that same conduct depends on the FDCA's existence." Couick, 2009 WL 4644394, at *5.

Likewise misplaced is Generic Defendants argument that the Supreme Court considered the fact that one of the defendants in *Mensing* had failed to include warnings appearing in the approved labeling for the drug, but still found preemption to apply. As stated by the court in *Fisher*:

> PLIVA argues in its brief that it brought to the Supreme Court's attention before oral arguments were held in Mensing that it may not have made changes that were approved for the Reglan label in July 2004. Because the issue was not raised at oral argument or in the Supreme Court's decision, PLIVA argues this possible deviation between the labeling for generic metoclopramide and the labeling for Reglan has no impact on the effect of the Mensing decision on this case.
>
> Contrary to PLIVA's assertion, this possible deviation impacts the Court's analysis of its motion to dismiss. Once the FDA approved the addition of these warnings to the Reglan label, PLIVA has not indicated that any federal law prevented PLIVA from also adding these warnings to its generic metoclopramide products.

Fisher Order, Ex. ??, pg.6. The Court also noted the unpersuasiveness of the argument advanced by PLIVA in a footnote:

> The plaintiffs also attached to their brief discussing the impact of the Mensing decision a letter from PLIVA's counsel, dated March 11, 2011, addressed to the Clerk of the United States Supreme Court. The letter states its purpose is to inform the Court that it appears at least some of PLIVA's post-2004 labels did not include the change made to the Reglan label in 2004. The letter also discusses PLIVA's opinion of the impact of this information. In doing so, the letter indicates a possible explanation for why the Supreme Court did not address the issue in its decision. More specifically, the letter states that Ms. Mensing last received PLIVA's metoclopramide product before the FDA approved the 2004 change to the Reglan label.

Id. at pp. 6-7, n. 4.

3. The Analysis of the Court in *Mensing* is Inapplicable to Claims Arising After Passage of the FDAAA

The *Mensing* court specifically disclaimed the applicability of its analysis and finding of preemption to any claim arising after the passage of the FDAAA. "All relevant events in these cases predate the Food and Drug Administration Amendments Act of 2007, 121 Stat. 823. We

therefore refer exclusively to the pre-2007 statutes and regulations and express no view on the impact of the 2007 Act." *Mensing,* 131 S.Ct. 2567, n.1. It is clear from the Court's decision that they found important the fact that *only* the brand-name manufacturer, not the generic manufacturers *or* the FDA, could change the content of the label of an approved drug:

> "we assume, federal law also required the Manufacturers to ask for FDA assistance in convincing the brand-name manufacturer to adopt a stronger label, so that all corresponding generic drug manufacturers could do so as well."
>
> "if the FDA had decided there was sufficient supporting information, and if the FDA undertook negotiations with the brand-name manufacturer, and if adequate label changes were decided on and implemented, then the Manufacturers would have started a Mouse Trap game that eventually led to a better label on generic metoclopramide."
>
> "Here, what federal law permitted the Manufacturers to do could have changed, even absent a change in the law itself, depending on the actions of the FDA and the brand-name manufacturer."
>
> "Federal law does not dictate the text of each generic drug's label, but rather ties those labels to their brand-name counterparts."
>
> "Thus, federal law would permit the manufacturers to comply with the state labeling requirements if, and only if, the FDA and the brand-name manufacturer changed the brand-name label to do so."
>
> "We often imagine that a third party or the Federal government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it."
>
> "… the Manufacturers' ability to comply with state law depended on uncertain federal agency and third-party decisions…"
>
> "Specifically, the CBE regulation, 21 CFR § 314.709(c)(6)(iii), permitted a brand-name drug manufacturer like Wyeth "to unilaterally strengthen its warning" without prior FDA approval."

Mensing, 131 S.Ct. at 2573, 2574, 2576, 2577.

After the passage of the FDAAA, the brand-name manufacturer was no longer the only entity that could bring about changes to the labeling for an approved drug. Whereas prior to the passage of the FDAAA, the FDA could only negotiate with the brand-name manufacturer to

change the content of its label, after the passage of the Act, it could impose such changes unilaterally, as it did with the labeling for Reglan in 2009. *See* February 26, 2009 letter from FDA mandating Black Box Warning for metoclopramide label, attached as Exhibit H. The United States in its *amicus* brief acknowledged the fact that the FDAAA could affect the preemption analysis employed by the Court:

> FDA now has authority under the Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85,121 Stat. 823, to require labeling changes based on new information from a variety of sources. See 21 U.S.C. 355(o)(4) (Supp. Ill 2009). FDA is currently developing guidance on how that authority will be exercised for changes to NDA and ANDA approved labeling. The existence of that authority and FDA's implementation of it could affect the preemption analysis of cases like these arising from events occurring after FDAAA's enactment.

Brief of the United States as *amicus curiae, PLIVA, Inc. v. Mensing*, at pg. 22, n.11.

The FDCA "generally **requires** the FDA to prevent the marketing of any drug or device where the "potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." *Food and Drug Admin. V. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000). "Contrary to the dissents assertion, the [FDCA] admits no remedial discretion once it is evident that the device is misbranded." *Id* at 135. Given the above, it is clear that after the passage of the FDAAA, if the Generic Manufacturers were to provide the FDA with information that its metoclopramide products were misbranded, there would be no uncertainty in the decision to be made by the FDA. It would be required to remove any misbranded product from the market until such time as the product was no longer misbranded. *Id*.

The result is that the decision to change the labeling for a generic drug would no longer depend on "uncertain federal agency and third-party decisions." Congress has mandated that the FDA shall withdraw approval of any misbranded drug, and in 2007 Congress gave them further power to change the content of the labeling. There is no uncertainty in the result that would be

obtained if a generic manufacturer provided the FDA with information that its drug was misbranded after the passage of the FDAAA – and therefore no preemption.

The linchpin of *Mensing's* analysis is that neither the Generic Manufacturers *nor* the FDA were capable of changing the content of the labeling of an approved drug to differ from that of the brand-name manufacturer prior to the passage of the FDAAA. Generic Defendants' assertion that it is the CBE provision that is the hallmark of the decision also belies the fallacy in their argument regarding their failure to include important safety information in their metoclopramide labels that already appeared in the labeling for the brand-name drug. There is no question that the CBE process was available to Generic Manufacturers to update their labels to include the 2003 and 2004 warnings regarding geriatric and long-term use. In that situation, the Generic Manufacturer could undoubtedly have made unilateral changes to their metoclopramide labels without any assistance from either the FDA or the brand-name manufacturer. The two arguments are fatal to each other.

4. Generic Defendants Could Have Satisfied Their State Law Duties By Ceasing to Sell Metoclopramide

Both the United States in its Brief as *amicus curiae* and the *Mensing* decision itself acknowledge that the argument that the Generic Manufacturers could have complied with state law by halting sales of their drugs were not before the Supreme Court:

> Drugs with FDA approval are presumptively lawful to sell in commerce. Respondents do not contend otherwise or suggest that petitioners' drugs simply should not have been available on the market.

Brief for the United States as *amicus curiae*, at pg. 25.

> In its decision below, the Eighth Circuit suggested that the Manufacturers could not show impossibility because federal law merely permitted them to sell generic drugs; it did not require them to do so. See *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they

> could have simply stopped selling the product"); see also *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000) (describing "a case of impossibility" as one "in which state law penalizes what federal law *requires* " (emphasis added)). Respondents have not advanced this argument, and I find it unnecessary to consider.

Mensing, 131 S. Ct. at 2588, n.8 (Sotomayor in dissent).

Generic Defendants' argument that the Supreme Court's denial of a rehearing in *Mensing* is "dispositive of that argument" lacks any legal basis or support. Contrary to Generic Defendants' Argument, "the denial of a petition for rehearing has no precedential value and is not a ruling on the merits of any issue between the parties." *Marshak v. Reed*, 229 F. Supp. 2d 179, 184 (E.D.N.Y. 2002) aff'd, 87 Fed. Appx. 208 (2d Cir. 2004); citing *Landreth v. Comm'r*, 859 F.2d 643, 648 (9th Cir.1988); *In re Grand Jury Investigation*, 542 F.2d 166, 173 (3d Cir.1976), *cert. denied*, 429 U.S. 1047, 97 S.Ct. 755, 50 L.Ed.2d 762 (1977). The only claim considered in *Mensing* was that the generic manufacturer should have changed the content of its label. As a generic manufacturer could not change its label by suspending its sales, the Court's analysis in *Mensing* is entirely consistent with Plaintiffs' argument that Generic Defendants had a *separate and distinct* duty to stop selling their drug once they realized it posed a significant danger to the public.

Generic Defendants' argument that a state law duty to stop selling a generic drug when it poses a health risk to the consuming public is entirely without merit. As stated above, ALL[20]

[20] Defendant Hospira, Inc.'s ("Hospira") Joinder in and Supplement to Generic Defendants' Preliminary Objections to Plaintiffs' Third Amended Complaint ("Hospira's Joinder") is equally without merit. First, without any support, Hospira makes a blanket statement that it is "most commonly used on a short-term basis in connection with certain medical procedures in an acute-care setting," ignoring that some Plaintiffs may have received the injectable version of Metoclopramide much longer, particularly, those given it to treat nausea associated with chemotherapy. *See* Hospira's Joinder, p. 2. Second, the injectable Metoclopramide label, like the other Manufacturing Defendants' labels, was still inadequate and if Hospira could not change it in accordance with *Mensing*, then it could have suspended sales while it was misbranded or advised the RLD holder that the label was inadequate and needed to be changed to reflect the true risks associated with injectable Metoclopramide. Indeed, Hospira's label today now contains the boxed warning regarding tardive dyskinesia, including a warning that usage for longer than 12 weeks should be avoided in all but rare cases, as required by the FDA in 2009. *See* http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=47908. Like the other Defendants, Hospira knew of the risks associated with Metoclopramide, of

manufacturers are required to suspend sales of their drugs (and foods, and cosmetics) if they learn that their labels for these products contain false or misleading information, or lack adequate warnings or instructions for use. This is the foremost and primary purpose of the FDCA. "Private remedies that enforce federal misbranding requirements [that products with labels containing information that is false or misleading should not be introduced into interstate commerce] would seem to aid, rather than hinder, the function of [the federal statute]. *Bates v. Dow Agrosciences*, 544 U.S. at 451. Furthermore:

> "The FDA has limited resources to monitor the 11,000 drugs on the market and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. 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."

Wyeth v. Levine, 129 S.Ct. 1187, 1202 (2009). Statutes such as the FDCA do not pre-empt any state rules that are fully consistent with federal requirements.

> In undertaking a pre-emption analysis at the pleadings stage of a case, a court should bear in mind the concept of equivalence. To survive pre-emption, the state-law requirement need not be phrased in the *identical* language as its corresponding [federal] requirement; indeed, it would be surprising if a common-law requirement used the same phraseology as [a federal statute].

Bates, 125 S.Ct. at 1802.

> As has been previously stated, when the Federal Food and Drug Act was initially passed,

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the inadequacy of its label, and of Metoclopramide's rampant off label use for years prior to the 2009 label change that was required by the FDA. Despite this knowledge, Hospira negligently and recklessly chose to continue to profit from the sale of its misbranded injectable Metoclopramide, as opposed to suspending its sales or requesting that the RLD holder change the label to adequately warn consumers, like the Plaintiffs. Therefore, Hospira cannot establish, ***with certainty***, that no recovery is possible for Plaintiffs who ingested its product. *See Koken v. Steinberg*, 825 A.2d 723, 726 (Pa. Commw. 2003) (it is well-established that preliminary objections must be denied unless "the law says ***with certainty that no recovery is possible***…To sustain preliminary objections a complaint must be clearly insufficient to establish any right to relief, and preliminary objections will not be sustained if any theory of law will support a claim."). Hospira's objections, like the other Defendants, should be denied in their entirety.

its sole purpose was to prohibit the introduction of adulterated and misbranded drugs into interstate commerce. Generic Defendants' argument that to require a manufacturer to withdraw its drug from the market if it learns that it is causing a public health crisis would "conflict with the statutory scheme" is patently absurd. Removing dangerous drugs from the market is the very reason that Congress passed the legislation and created the FDA. Generic Defendant's argument that lay juries are not allowed to second-guess the decisions of the FDA has also been flatly rejected by the Supreme Court. "Moreover, because the [FDCA] contemplates that federal juries will resolve most misbranding claims, the FDA's belief that a drug is misbranded is not conclusive." *Wyeth v. Levine*, 129 S.Ct. at 1197, citing 21 U.S.C. §§ 331, 332, 334(a)-(b); *See also, Bates*, 125 S.Ct. at 1803 ("Moreover, it bears noting that lay juries are in no sense anathema to FIFRA's scheme: In criminal prosecutions for violations of FIFRA's provisions, see § 136l(b), juries necessarily pass on allegations of misbranding.").

Failing to find immunity under *Mensing*, Generic Defendants abandon impossibility preemption and attempt to chart new territory by asking the Court to find that holding generic manufacturers liable for the damage they cause would "stand as an obstacle to Congress' goal of making low-cost medicines available to the public." Leaving aside for the moment the fact that Congress expressed no desire for cheap, ineffective and dangerous drugs, Generic Defendants' argument only considers one of the reasons Congress passed the Hatch-Waxman amendments. As is clear from the very title of the law (Drug Price Competition *and Patent Restoration Act*), Congress had dual purposes in passing the Hatch-Waxman amendments. The first, identified by the Generic Defendants, was to make it easier for generic drug companies to gain FDA approval to market their drugs in order to encourage competition among manufacturers. The second goal was to provide incentive to manufacturers who develop safer, more effective new drugs by

extending the length of their patent exclusivity.

In effect, Generic Defendants argue that Congress intended for them to flood the market with drugs that were more dangerous and less effective than alternative therapies on the market, and to immunize them from liability when they actively misrepresent and conceal the fact that their drug is dangerous and ineffective. Clearly, this is not the scheme envisioned by Congress. No matter how Generic Defendants try to avoid it, there was simply nothing stopping them from ceasing sales of their drug when they learned there was a problem. Nothing, that is, except the steady stream of income Generic Defendants generated through sales of metoclopramide.

5. Approaching the NDA Holder to Correct False Statements Appearing in the Label for Metoclopramide Is Part of Generic Manufacturers' Duty to Exercise Reasonable Care

While approaching either the FDA or the brand name manufacturer would not have satisfied a duty to change the content of the labeling for a generic drug, such action could satisfy Generic Defendants' duty to exercise reasonable care in the production, marketing and sale of their metoclopramide products. Furthermore, the United States in its *amicus* brief stated unequivocally that Generic Manufacturers have a duty under federal law to take action if they learn that their drugs pose a threat to consumers:

> Information on the risks and benefits associated with a drug may accumulate over time. Accordingly, NDA and ANDA holders must keep records of clinical experiences and ensure that their drugs remain safe and effective as labeled. In particular, implementing regulations provide that a manufacturer must record and report certain adverse events to FDA, and must also annually report a summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product and a description of actions the applicant has taken or intends to take as a result of that new information.

Brief for United States as *amicus curiae,* pg. 6 (internal citations omitted). The FDA characterized the actions required of a generic manufacturer as follows:

> FDA regulations require NDA holders and ANDA holders alike to act upon new safety information that warrants added or strengthened warnings. Petitioners are correct that, in meeting that federal duty, they could not properly have invoked the CBE or PAS process, or sent the sort of DHCP letter respondents envision. But ANDA holders nonetheless should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.

Id at pg. 12.

Plaintiffs allege not only that Generic Defendants were negligent in failing to approach the brand-name manufacturer, but also that they were negligent in failing entirely to comply with any of the above stated requirements of federal law. In short, Generic Defendants did *nothing* to evaluate the truth of statements appearing in their label, and failed to take *any action* to curb a public health crisis that had been repeatedly reported in sources readily available to them. Instead, they remained willfully ignorant of the problem they were causing, and chose to continue profiting from the sale of a product that was causing serious irreparable injury to those that consumed it.

There is nothing, no federal law, no statute, no regulation that prohibited the Generic Defendants from approaching the manufacturer of the brand-name drug regarding the safety issues posed by false and inadequate labeling. Nor does any provision of law identified by Generic Defendants prevent them from taking any other action, besides changing the active ingredient, route of administration, or labeling for their drug to differ from that of its brand-name equivalent. The result is that these actions are not preempted. The question of whether Plaintiffs would be able to prove proximate cause based solely on the failure of Generic Defendants to approach the brand manufacturer is a question not before the Court, but suffice it to say that there were numerous avenues and actions available to Generic Defendants that could have prevented the injuries suffered by Plaintiffs. They chose to do absolutely nothing. Plaintiffs' allegation that Generic Defendants should have approached the brand name manufacturer is not preempted,

it is but one piece of evidence showing that they were negligent in the manner in which they manufactured, marketed, and sold their metoclopramide products.

6. Design Defect Claims Are Not Preempted

The *Mensing* decision does not consider claims for the defective design of a drug. The only claim considered by the Court was that a generic manufacturer should have changed the content of the labeling for its drug. State laws that "require manufacturers to design reasonably safe products … plainly do not qualify as requirements for labeling…" *Bates*, 125 S.Ct. at 1798.

While the "sameness" requirement at issue in *Mensing* does apply to the chemical formulation and labeling of a generic drug, it does not apply to other aspects of the design of the generic drug product, such as packaging. Furthermore, it is unnecessary for Plaintiffs' to show that Generic Defendants should have altered the design of their product in order to prove their claim. Rather, Plaintiffs need only prove that, as designed, the risks associated with the use of metoclopramide outweighed the benefits to be derived. In any event, Plaintiffs' TAMLFC alleges that there existed safer packaging alternatives that could have prevented the injuries caused by metoclopramide. As a result, Generic Defendants' failure to incorporate such packaging into the design of its product would render them subject to liability for defective design of their metoclopramide products.

21 U.S.C. § 355(j), the federal statute that requires the labeling for a drug to match that of its brand-name counterpart also prohibits the FDA from imposing the requirement of "sameness" on any aspect of a generic drug other than (1) its active ingredients; (2) the route of administration, dosage form or strength of the drug; and (3) the labeling for the drug. 21 U.S.C. § 355(j)(2)(a)(ii),(iii),(v) ("The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii)"). Nothing in either the

FDCA or Hatch-Waxman amendments require Generic Defendants to market or sell their drugs. To the contrary, if the brand-name version of a drug is misbranded, the generic equivalent is also misbranded, and introducing the product into interstate commerce violates federal law. *See* Brief of United States as *amicus curiae*, *PLIVA v. Mensing*, at pp. 22-29.

In addition the "ordinary meaning" of the federal law at issue in *Mensing* requires only that a generic drug be the same as its brand-name counterpart with respect to its active ingredients, route of administration, dosage form, strength and labeling. Plaintiffs' admit that any claim that the generic manufacturers should have unilaterally altered any of these aspects of their metoclopramide products are preempted under *Mensing*. *Mensing* does not, however, serve to preempt claims based upon any other actions that could have been taken by the Generic Defendants.

7. <u>All of the Counts in Plaintiffs' Complaint Survive Preemption Under the Court's Analysis in *Mensing*</u>

Generic Defendants have failed to point to a single requirement of federal law that would have prevented them from taking any of the actions upon which Plaintiffs' base their claims. Instead, they ask the Court to determine that all of Plaintiffs' claims are preempted by virtue of the fact that a generic manufacturer cannot unilaterally change the content of its label. Further revealing the weaknesses in their argument, Generic Defendants do not identify a single state law that would require them to change the content of their labels. As a result, all of Plaintiffs claims appearing in their TAMLFC are unaffected by the Supreme Court's decision in *Mensing*.

While Plaintiffs have consistently alleged that Generic Defendants placed their metoclopramide products into the hands of consumers without providing warnings or instructions that were adequate to promote safe use of the drug, they have also consistently alleged that Generic Defendants: (1) made false and misleading statements and representations

designed to encourage dangerous off-label use of metoclopramide; (2) placed their metoclopramide products into the stream of commerce knowing that a significant number of individuals were likely to be harmed as a result of their false statements; (3) failed to fulfill their obligations to properly test or inspect their product; (4) failed to review publicly available information identifying the serious problem posed by metoclopramide; (5) failed to fulfill their obligations to report all necessary information regarding their products to the appropriate parties.

Likewise, Plaintiffs have consistently alleged that (6) metoclopramide is unfit for the uses for which it was being prescribed, (7) Generic Defendants were aware of both this fact and the fact that it was common practice among physicians to prescribe metoclopramide for longer than 12 weeks, and (8) Generic Defendants actively concealed and suppressed information identifying the danger posed by the drug and the frequency with which injuries occurred. "The fact that these alleged misrepresentations were unaccompanied by additional statements in the nature of a warning does not transform the claimed fraud into failure to warn." *Altria*, 129 S.Ct. at 542.

As Generic Defendants' Objections identify no law that they believe pertain to the claims, their discussion of the individual claims is an exercise in futility. In order to perform a preemption analysis, a court must compare the federal law to the state law which may possibly be preempted. If there is no state law to examine, there can be no conflict. Still, Plaintiffs shall endeavor to respond to Generic Defendants arguments, nonsensical though it may be.

COUNT I – STRICT LIABILITY

The clear holding of the Supreme Court in *Mensing* is that claims based upon the duty of a generic manufacturer to change the content of their drug are preempted by the federal duty of sameness found in 21 U.S.C. 355(j). As addressed above, *Mensing* in no way precludes a claim that Generic Defendants should have provided warnings appearing in the approved labeling for

metoclopramide to physicians, or anyone else. The only prohibition placed upon Generic Manufacturers by the Hatch-Waxman amendments is that they are not allowed to unilaterally alter the labeling for their drugs. Generic Defendants failure to provide warnings prohibiting long-term use to the physicians prescribing their drugs subjects them to strict liability. The claims contained in Count I are different and distinct than the claim considered by the Supreme Court in *Mensing*. Namely, Plaintiffs allege Generic Defendants should be held liable for *selling* their drug, and for failing to *provide* or *communicate* the warnings already appearing in the labeling for the brand-name drug that indicated use of the drug should not exceed 12 weeks in duration, along with other important safety information, the existence of which was unknown to both prescribers and consumers of the drug. *Mensing* does not provide that such claims are preempted.

Section 402A of the Restatement (Second) of Torts, pertaining to strict liability, provides, in relevant part, that "[o]ne who **sells** any product in a defective condition unreasonably dangerous to the user or consumer … is subject to liability thereby caused to the ultimate user or consumer." (emphasis added); *See also Borel*, 493 F.2d at 1087. A product is "defective" under the Restatement only if it "unreasonably dangerous" to the user or consumer. *See* Wade, Strict Tort Liability of Manufacturers, 19 S.W.L.J. 5, 14-15 (1965). A product is "unreasonably dangerous" only when it is "dangerous to an extent beyond that contemplated by the ordinary consumer who purchases it." Restatement (Second) of Torts §402A, comment i. Thus, for a product to be unreasonably dangerous, it must be so dangerous that ***a reasonable man would not sell the product if he knew the risk involved."*** *Borel*, 493 F.2d at 1088; *see also* Wade, Strict Tort Liability of Manufacturers, 19 S.W.L.J 5, 15 (If the defendant has actual or constructive knowledge of the condition of the product, it would be unreasonable for him to sell it). As a

result, Plaintiffs' strict liability claims against Generic Defendants are not based upon allegations that they should have changed the contents of their labels, but rather that they should not have sold their metoclopramide products, as they were unreasonably dangerous. Such a claim was not before the Court in *Mensing,* and is not preempted by the federal duty of "sameness."

Neither federal law nor state law required the Generic Defendants to sell metoclopramide, and they could have easily complied with their duty not to sell unreasonably dangerous products by ceasing to sell metoclopramide. Furthermore, Plaintiffs allege that Generic Defendants *never provided any warning* to either the medical community, or those who consumed their drugs. Given the fact that Plaintiffs generally allege that the injuries they suffered were the result of long-term metoclopramide use, the failure of the Generic Defendants to alert the medical community of the fact that therapy with metoclopramide "**should not exceed 12 weeks in duration**" (a warning that appeared in the brand name label for the drug, but which was never included in Defendants' labeling, or communicated to physicians or consumers) also

The adequacy of a warning is a factual determination that depends on the individual facts of each case. If giving Plaintiffs or their prescribing physicians information or warnings that appeared in the approved labeling for the brand-name drug would have caused them to stop using metoclopramide, then such warning would be adequate. This would be so even though the labeling also contained false statements that underestimated the risk of side effects.

COUNT II – STRICT LIABILITY – DESIGN DEFECT

Defendants design defect claims are not based solely on the fact that Generic Defendants' metoclopramide products lacked adequate warnings. Furthermore, *Mensing* considered only considered claims that a generic manufacturer should have changed the content of its label to add warnings different or in addition to those appearing in the label of the brand name drug.

Mensing is silent with regard to preemption of design defect claims. State laws that "require manufacturers to design reasonably safe products … plainly do not qualify as requirements for labeling…" *Bates,* 125 S.Ct. at 1798.

As acknowledged in Generic Defendants' Preliminary Objection #75, Plaintiffs have alleged that the manner in which Generic Defendants' packaged their metoclopramide products rendered their products unreasonably dangerous. *Mensing* does not speak to design defects, and the federal duty of "sameness" with regard to generic drugs does not apply to packaging. Furthermore, as with the strict liability claims appearing in Count I of Plaintiffs' TAMLFC, Generic Defendants could have complied with their duties under a state's strict liability laws by refraining from selling the drug. Generic Defendants have not indicated any law that would require Plaintiff's to show the existence of a feasible alternative design, and such a showing is unnecessary in order to prevail on a claim of strict liability for design defect.

Furthermore, as acknowledged by Generic Defendants, the only aspects of a generic drug's design that are required to be "the same as" those of the brand name drug are the active ingredient, route of administration, dosage form, strength and labeling. The duty of sameness does not apply to a generic drug's packaging, which Generic Manufacturers could have differed from the brand name drug at the time of approval, or made unilateral changes to thereafter.

COUNT III – NEGLIGENCE

Defendants provide no support for their proposition that *Mensing* precludes negligent failure to warn claims. As has been discussed previously, the sole claim at issue in *Mensing* was that the generic defendant should have changed the labeling for its metoclopramide product. *Mensing* did not consider claims that a manufacturer failed to exercise reasonable care in testing, marketing, labeling, selling, or any of their other activities with respect to metoclopramide. In

addition, common-law negligence claims impose only the duty to exercise reasonable care, they do not require a manufacturer to take any specific action to be taken. As a result, as long as Generic Defendants actions were reasonable, they would not be subject to liability.

Generic Defendants do not define what a "straightforward failure to warn claim" is, nor do they cite to any provision of state law supporting such a statement. To the extent that the failure of the Generic Manufacturers to include important safety related information already approved by the FDA in the labels for their metoclopramide products are considered failure-to-warn claims, these claims parallel the requirements imposed by the federal government that the labeling for generic drugs to include labeling changes made by the RLD because "prompt revision, submission to the Agency, and implementation of revised labeling are important to ensure the continued safe and effective use of generic drug products." Guidance for Industry, Revising ANDA Labeling Following Revision of the RLD Labeling, May 2000, attached hereto as Exhibit G.

Generic Defendants make no argument that they were not required to test and inspect their product, familiarize themselves with the effect their metoclopramide products had in consumers, cease the sale of their drugs when they learned that their metoclopramide products contained false and misleading information, and lacked adequate warnings and instructions for use. They likewise do not claim that they were not required to monitor the medical and worldwide scientific literature, evaluate the accuracy and adequacy of statements appearing in the label of their metoclopramide products or to approach the FDA and/or brand-name manufacturer if they learn that their drug is misbranded or that there is a serious safety issue. Further, Generic Defendants failed to include warnings in the labeling of their metoclopramide products that appeared in the label for the brand-name drug directed at curbing use of the drug in

geriatric patients and for longer than12 weeks, and even if they did include these statements in their labeling, they failed to alert physicians and consumers to the presence of the strengthened warnings. Generic Defendants' failure to take any of these actions breached their duty to exercise reasonable care in the manufacture, marketing and sale of metoclopramide. Such claims were not before the Court in *Mensing.*

COUNT IV – NEGLIGENCE *PER SE*

Plaintiffs' negligence *per se* claims would, by definition be considered "parallel claims" to the extent that the premise for liability is the failure of Generic Manufacturers to comply with the standard of care dictated by provisions of federal law.

> We must also reject respondent's attempt to characterize both the claims at issue in *Medtronic* (common-law negligence action against the manufacturer of an allegedly defective pacemaker lead) and the fraud claims here as "claims arising from violations of FDCA requirements." Notwithstanding the fact that *Medtronic* did not squarely address the question of implied pre-emption, it is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. *See* 518 U.S. at 481, 116 S.Ct. 2240. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

Medtronic, Inc. v. Lohr, 116 S.Ct at 2255.

Plaintiffs' claims regarding the failures of Generic Defendants to perform required pharmacovigilance activities or monitor the worldwide literature should have alerted them to the fact that their drug was misbranded and/or posed a public health hazard. Their failure to report appropriate information deprived the FDA of information which would have required them to withdraw the drug from the market if the brand-name manufacturer refused to change the content of its label. Furthermore, Generic Defendants failure to apprise themselves of the effect their products were having on consumers resulted in complete ignorance to a public health crisis, and

the knowledge that the labeling for their metoclopramide products contained false and misleading statements which obliged them to stop selling the product.

These claims do not derive from federal law, but rather from the Generic Defendants' state law duty to exercise reasonable care in conducting their activities. The federal statutes and regulations that govern the conduct set the standard of care for Generic Defendants, and their violations of these provisions of law serve as proof of the unreasonableness of their conduct. Furthermore, Plaintiffs allege that Generic Defendants' activities violated not only federal law, but state law as well. Many states have enacted independent provisions of law that parallel the requirements placed upon Generic Defendants by the FDCA. Clearly, enforcement of these statutes is not within the exclusive province of the federal government.

Claims for negligence *per se* are distinct from traditional negligence claims in that they utilize applicable federal and state statutes and regulations to define the standard of care to which Generic Defendants must adhere. Furthermore, when the standard of care is defined by a provision of federal law, a claim for negligence *per se* is the equivalent of a "parallel claim" under a state's law.

COUNT V – FRAUD MISREPRESENTATION AND SUPPRESSION

Mensing did not consider fraud, misrepresentation or suppressions claims such as those presented in Count V of Plaintiffs' TAMLFC, the Court only considered the claim that the generic manufacturers should have unilaterally changed the content of their labels for metoclopramide.

Plaintiffs' TAMLFC alleges not only that Generic Defendants participated in the active misrepresentation of the brand defendants by adopting and incorporating false and misleading statements into their own labels for metoclopramide, but also that they themselves actively

suppressed important information that they were under a duty to disclose. Furthermore, Generic Defendants have a duty to be an expert in their product, and therefore, even if they were actually unaware that the statements appearing in their labels were metoclopramide, this came as a result of their decision to remain willfully ignorant of the properties of their metoclopramide products. Federal law provides that information relating to the safety and efficacy of a drug appearing in the New Drug Application for the brand-name drug is made publicly available prior to the time of approval of the first generic equivalent. 21 C.F.R. § 314.430. Therefore the information indicating that the basis upon which metoclopramide received marketing approval was false and unscientific was available to the Generic Defendants since the day the first generic version was approved, and state law required them to apprise themselves of that information.

Finally, fraud includes not only positive misstatement of facts, but also remaining silent when there exists a duty to speak. Here, Generic Defendants were obliged to at least inform the FDA of the fact that the labeling of their drug contained false and misleading statements. Furthermore, Generic Defendants were obliged to inform consumers of the fact that their metoclopramide products were unlikely to be safe or effective in long term use, and that approval for marketing of the drug had been fraudulently obtained, or to stop selling the product.

If Generic Manufacturers introduced their metoclopramide products into interstate commerce, they were required to accompany these products with adequate warnings and instructions for use that were free from statements that were false and misleading. *Mensing* does not permit a generic manufacturer to knowingly misrepresent the risk profile of its drug and actively encourage dangerous off-label use because they could not unilaterally change the content of their metoclopramide labels. If they could not provide truthful and accurate information about how to use the product safely, they were obliged not to market the drug.

Plaintiffs' have sufficiently alleged that Generic Defendants engaged in actions that constitute misrepresentation, fraud and suppression. Generic Defendants have identified no federal law that required them to sell their metoclopramide products when its labeling contained information that was false, misleading, and lacked adequate warnings and instructions for use. Furthermore, Generic Defendants have identified no state law under which Plaintiffs factual allegations would be insufficient to prove misrepresentation, fraud or suppression, and have therefore failed to show that they are entitled to dismissal of these claims.

COUNT VI – CONSTRUCTIVE FRAUD

Mensing did not consider claims fraud, misrepresentation or suppressions claims such as those presented in Count VI of Plaintiffs' TAMLFC, the Court only considered the claim that the generic manufacturers should have unilaterally changed the content of their labels for metoclopramide. As stated above, Plaintiffs' TAMLFC alleges not only that Generic Defendants participated in the active misrepresentation of the brand defendants by adopting and incorporating false and misleading statements into their own labels for metoclopramide, but also that they themselves actively suppressed important information that they were under a duty to disclose, or remained willfully and recklessly ignorant of the fact that their drug was causing harm to individuals due to false and misleading statements appearing therein, and Generic Defendants' conscious decision to remain silent and continue marketing the drug.

COUNT VII - BREACH OF EXPRESS AND IMPLIED WARRANTIES

The United States Supreme Court has never found a claim for breach of express warranty to be preempted by federal law. This is because the Court has determined that "a common-law remedy for a contractual commitment voluntarily undertaken should not be regarded as a '*requirement … imposed under state law*.'" *Cipollone*, 505 U.S. at 526. The Court has

additionally held that "[r]ules that require manufacturers to … honor their express warranties or other contractual commitments plainly do not qualify as requirements for "labeling." *Bates*, 544 U.S. at 444.

When Generic Defendants voluntarily undertook to market and sell metoclopramide, they subjected themselves to liability for the warranties they provided regarding their product. The fact that they could not unilaterally change the content of their label does not change this analysis:

> To be sure, Dow's express warranty was located on [the product's] label.[21] But a cause of action on an express warranty asks only that a manufacturer make good on the contractual commitment that it voluntarily undertook by placing that warranty on its product. Because this common-law rule does not require the manufacturer to make an express warranty, or in the event that the manufacturer elects to do so, to say anything in particular in that warranty, the rule does not impose a requirement for "labeling or packaging."
>
> In arriving at a different conclusion, the court below reasoned that a finding of liability on these claims would "induce Dow to alter [its] label." This effects-based test finds no support in the text of [the federal statute], which speaks only of "requirements." A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants."

Generic Defendants provide no support for their statement that breach of warranty claims do not fit the prescription drug context. Courts have long found that manufacturers of prescription drugs may be held liable for breach of warranties, both express and implied, when the drug causes personal injuries. *See, e.g. Castrignano v. E.R. Squibb & Sons, Inc.*, 900 F.2d 455 (1st Cir. 1990); *Tinnerholm v. Parke, Davis & Co.*, 411 F.2d 48 (2nd Cir. 1969); *Bogorad v.*

[21] Like the Generic Defendants, the federal statute at issue in *Bates* did not permit Dow to alter the content of its label without prior FDA approval. *Id* at 438-439.

Eli Lilly & Co., 768 F.2d 93 (6th Cir. 1985); *Parke, Davis & Co., v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969).[22] Furthermore, the FDA does not regulate the uses to which prescription drug products are put by licensed physicians, it only regulates the uses for which a manufacturer may market and promote the drug. Plaintiffs' TAMLFC alleges that Generic Defendants marketed and promoted metoclopramide for long-term use, despite the fact that the FDA had never approved use of the drug for such length of time. Likewise, the Generic Manufacturers marketed the drug for use in chronic conditions, with full knowledge that physicians were engaging in highly dangerous long-term use to treat these conditions. Claims for breach of implied warranties require

COUNT VIII – UNFAIR AND DECEPTIVE TRADE PRACTICES

Mensing did not consider claims for unfair and deceptive trade practices such as those appearing in Count VIII of Plaintiffs' TAMLFC. The Court only considered the claim that generic manufacturers should have unilaterally changed the content of their labels for metoclopramide. Furthermore, the U.S. Supreme Court has specifically rejected the argument advanced by Generic Defendants that claims against a manufacturer under unfair trade practices are in fact failure to warn claims. Acknowledging that the same actions may subject a manufacturer to liability under multiple different theories, the Court in *Altria* stated, "respondents' claim that the deceptive statements … induced them to purchase petitioners' product alleges a breach of the duty not to deceive. To be sure, the presence of federally mandated warnings may bear on the materiality of petitioner's allegedly fraudulent statements, 'but that does not change [respondents'] case from one about the statements into one about the

[22] For more recent cases, *see McCauley v. Hospira, Inc.*, 2011 WL 3439145 (M.D. N.C. 2011); *Gray v. Abbott Laboratories, Inc.*, 2011 WL 3022274 (N.D. Ill. 2011); *Lee v. Mylan, Inc.*, 2011 WL 1458160 (M.D. Ga. 2011); *In re Hydroxycut Marketing Sales Practice Litigation*, 2011 WL 2135232 (S.D. Ca. 2011); *Moss v. Walgreen Co.*, 765 F.Supp.2d 1363 (S.D. Fla. 2011).

warnings.'" 129 S.Ct at 547.

Plaintiffs allege that Generic Defendants are liable for their active participation in unfair and deceptive trade practices by deriving benefit from misrepresentations and fraud which they themselves engaged in by promoting their drug for uses which were not approved by the FDA, and which were likely to lead to injury in those who consumed their metoclopramide products. Furthermore, Plaintiffs allege that Generic Defendants knowingly represented that their metoclopramide had a much lower risk of side effects than was actually true, and that they made these representations with reckless disregard for the safety of others.

COUNT IX - UNJUST ENRICHMENT

Mensing did not consider claims for unjust enrichment such as those appearing in Count IX of Plaintiffs' TAMLFC. The Court only considered the claim that generic manufacturers should have unilaterally changed the content of their labels for metoclopramide. Plaintiffs complaint alleges that Generic Defendants benefitted from the initial misrepresentations made by brand defendants, and knowingly chose to benefit from these wrongful actions by continuing to derive profits from metoclopramide sales to individuals whom they were aware were relying upon false information included in the labeling for their metoclopramide products. Generic Defendants are liable to Plaintiffs for the profits they received from these actions.

The basis for the unjust enrichment claim is that Generic Defendants knowingly sold a product that they know was neither safe nor effective in the uses for which it was being purchased and consumed. Furthermore, Generic Defendants' provide no citation or justification for their statement that Plaintiffs' unjust enrichment claim is "an attack on Generic Defendants' warnings", nor do they identify any provision of federal law which required them to knowingly sell a drug that was neither safe nor effective for the uses to which it was being put. Absent such

a showing, Plaintiffs' unjust enrichment claims are not preempted.

COUNT XI – CIVIL CONSPIRACY

Plaintiffs' TAMLFC alleges that Generic Defendants acted with a common purpose to intentionally and/or fraudulently withhold information from the medical community for the purpose of receiving continued financial benefit from sales of metoclopramide. *Mensing* did not consider claims for civil conspiracy such as those appearing in Count IX of Plaintiffs' TAMLFC. The Court only considered the claim that generic manufacturers should have unilaterally changed the content of their labels for metoclopramide.

As is apparent from the allegations in Plaintiffs' TAMLFC, Generic Defendants' liability for civil conspiracy is based not only on misbranding, but is also based on Generic Defendants' efforts to conceal important safety information from the medical community in order to continue profiting from metoclopramide sales. Furthermore, a drug is misbranded not only when it lacks adequate warnings, but also when it contains false or misleading information in its label. Finally, the Supreme Court has repeatedly held that state law claims that parallel federal requirements (such as the federal requirement that a manufacturer shall not introduce a misbranded drug into interstate commerce) are not preempted. Federal law "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." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330, citing *Lohr*, 518 U.S. at 495.

COUNT XII – LOSS OF CONSORTIUM

As Plaintiffs' underlying claims are not preempted, their loss of consortium claims are likewise not preempted.

COUNT XIII – WRONGFUL DEATH

As Plaintiffs' underlying claims are not preempted, their wrongful death claims are likewise not preempted.

COUNT XIV – SURVIVAL ACTION

As Plaintiffs' underlying claims are not preempted, their survival claims are likewise not preempted.

VII. RELIEF REQUESTED

For those reasons set out in the above Memorandum, Plaintiffs respectfully request that the Master Preliminary Objections to Plaintiffs' Third Amended Complaint For Damages On Behalf of Generic Defendants be DENIED.

Respectfully submitted,

PLAINTIFFS' LIAISON COMMITTEE

BY: /s/ Rosemary Pinto
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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Plaintiff's Response in Opposition to Defendants' Petition for Permission to Appeal was served on all parties in the above captioned matter and/or their counsel of record by e-mail with the agreement for the party being served, pursuant tot he case management orders governing service in the litigation:

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