IN RE	:	
	:	COURT OF COMMON PLEAS
REGLAN/METOCLOPRAMIDE LITIGATION	:	PHILADELPHIA COUNTY
	:	
This Document Relates to All Cases	:	
	:	
PLAINTIFFS	:	JANUARY TERM, 2010
	:	NO.: 01997
Plaintiffs,	:	
	:	
vs.	:	
	:	
WYETH LLC, *et al*.,	:	
	:	
Defendants.	:	

ORDER

AND NOW, this _____day of _____, 2011, upon consideration of the Master Preliminary Objections filed on behalf of Generic Defendants, and Plaintiffs' Response in Opposition thereto, it is hereby ORDERED and DECREED that Generic Defendants' Preliminary Objections are **DENIED**.

BY THE COURT:

_____
Judge Sandra Mazer Moss

Executive Summary of Plaintiffs' Response to Generic Defendants Preliminary Objections

The Generic Defendants have filed preliminary objections to Plaintiffs' Third Amended Complaint, asserting that all of the claims alleged therein are preempted by the ruling of the Supreme Court in *Pliva, Inc. v. Mensing.* In making their argument, the Generic Defendants ask this Court to assume (without providing any justification) that:

1. All of Plaintiffs' claims against the Generic Manufacturers would require these Defendants to change the content of their labeling in order to comply with state law;

2. That the labeling of a generic drug, even if never provided to physicians and consumers, is sufficient to constitute a "warning";

3. That selling a drug accompanied by information that falsely underestimates the risks its poses and which invites dangerous off-label use is the same as failing to provide an adequate warning; and

4. That generic drug manufacturers are entitled to market and sell drugs for uses that have never been approved by the FDA, despite being aware of the fact that these uses were likely to result in serious injury to those who used their products.

Contrary to the arguments advanced by the Generic Defendants, the *only* theory of liability before the court in *Mensing* was the Plaintiff's claim that the generic manufacturers should have changed the content of their labeling in order to provide adequate warnings regarding the effects of their drugs. The result is that *Mensing* serves to preempt only the single claim considered by the Court (one type of failure-to-warn claim). The decision does not affect any claim against a generic manufacturer that does not require the specific action of changing the content of their drug's label.

Plaintiffs' concede that any claim that a generic manufacturer should have changed the content of their metoclopramide label to add, delete or change information is preempted under *Mensing*, and as a result, their Complaint makes no such allegation. Instead, Plaintiffs allege that there were numerous actions other than a labeling change available to the Generic Defendants that were permitted under federal law that would have prevented Plaintiffs' injuries. If state law requires these actions to be taken, and they are not prohibited by federal law, then such claims are not preempted. Furthermore, *Mensing*'s finding of preemption with respect to one type of failure-to-warn claim has absolutely no bearing on the other claims asserted by Plaintiffs, such as fraud, misrepresentations, design defect, breach of warranty, and unfair trade practices. Defendants bare assertion that these distinctly different claims are based on a "failure to warn" is completely unsupported, and the US Supreme Court has rejected such an approach to resolving questions of preemption.

Finally, the Generic Defendants acknowledge that their Preliminary Objections do not address the requirements placed upon them by the laws of *any* state. In doing so, they effectively acknowledge that their objections are premature. As the determination of whether a particular claim is preempted by federal law depends *entirely* upon the requirements imposed upon the Generic Defendants by state law, the Court cannot properly make a determination of preemption without first determining the law upon which such claims are based. Nonetheless, no law

prohibits claims of the Plaintiffs alleging that the Generic Defendants should have communicated their FDA approved label to physicians, the medical community and consumers, like the Plaintiff, or engaged in risk minimization strategies, like Medication Guides, or suspended sales of their drugs while misbranded. Generic Defendants cannot establish, ***with certainty,*** that no recovery is possible for Plaintiffs who ingested their products. *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."). All Generic Defendants' objections should be denied in their entirety.

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

Plaintiffs in the above-captioned consolidated cases, through the undersigned attorneys, hereby respond in opposition to the Master Preliminary Objections of Generic Defendants to Plaintiffs' Third Amended Complaint, and in support thereof, aver as follows:

INTRODUCTION

On July 11, 2011, this court in the In RE: Reglan®/Metoclopramide Litigation granted Plaintiffs leave to amend the Master Long Form Complaint based upon United States Supreme Court's decision in *PLIVA, Inc., et al. v. Mensing*. A true and correct copy is attached hereto as Exhibit "A". Pursuant to the Court's Order, Plaintiffs filed a Third Amended Master Long Form Complaint (TAMLFC) on August 1, 2011. A true and correct copy is attached hereto as Exhibit "B". On September 8, 2011, the Generic Defendants filed preliminary objections to Plaintiffs' Third Amended Long Form Complaint, asserting that all of the claims stated therein should be dismissed by virtue of the *Mensing* decision. A true and correct copy is attached hereto as Exhibit "C".

Contrary to the arguments appearing in the Generic Defendants' Preliminary Objections:

1. The claims alleged in Plaintiffs' TAMLFC are entirely different than those considered by the Supreme Court in *Mensing*, and do not consist solely of claims premised on the Generic Defendants' failure to warn.

2. The "failure to warn" claims that Plaintiffs have alleged in their TAMLFC contain no allegation that the Generic Defendants should have unilaterally changed the content of the labels accompanying their metoclopramide products, or provided any information to physicians or consumers that did not already appear in the labeling for Reglan, the brand-name equivalent of metoclopramide.

RESPONSE TO PRELIMINARY OBJECTIONS

1. Admitted in part and denied in part. It is admitted that Plaintiffs filed a Master Long Form Complaint on or about March 18, 2010 based upon numerous theories of liability. It is also admitted that, in general, the causes of action are based on Plaintiffs' development of movement disorders resulting from their ingestion of Reglan or metoclopramide. Generic Defendants characterization of the claims appearing in the complaint is denied and the complaint as a properly plead document speaks for itself.

2. Admitted that Plaintiffs filed amended complaints on or about April 23, 2010 and February 25, 2011.

3. Admitted in part and denied in part. It is admitted that the United States Supreme Court issued its decision in *PLIVA, Inc. v. Mensing* on June 23, 2011, finding that the specific claim asserted by plaintiff – that the generic manufacturers should have changed the content of the labeling for their metoclopramide products - was preempted. Defendants' characterization of the holding in *Mensing* as preempting any or all failure to warn claims is denied.

4. Admitted in part and denied in part. It is admitted that Plaintiffs filed their TAMLFC on or around August 1, 2011. The remainder of the allegations are denied in that permission was granted for the purpose of eliminating and clarifying causes of action alleged against the various defendants in order to comport with the *Mensing* decision.

5. Denied. While certain causes of action appearing in Plaintiffs' TAMLFC may be based on a generic manufacturer's duty to warn of the dangerous characteristics of its drug products, the vast majority are not. Specifically, Plaintiffs deny that their claims for design defect, negligence, negligence *per se,* fraud, misrepresentation and suppression, constructive fraud, breach of express and implied warranties, unfair and deceptive trade practices, unjust

enrichment, civil conspiracy, loss of consortium, wrongful death, and survival action are all based on a theory of failure-to-warn. Furthermore, those claims that are based upon the Generic Manufacturers' duty to provide adequate warnings do not allege that the content of their metoclopramide labeling should have been unilaterally altered to provide a safer warning. Generic Defendants' Preliminary Objections to Plaintiffs' TAMLFC should be denied.

ARGUMENT

6. Admitted as a conclusion of law to which no responsive pleading is required under the applicable Pennsylvania Rules of Civil Procedure. By way of further response, preliminary objections the end result of which would be dismissal of a cause of action, should be sustained only in cases that are clear and free from doubt. *Baker v. Brennan*, 419 Pa. 222, 225, 213 A.2d 362, 364 (1965). In addition, 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 cliam." *See Koken v Steinberg,* 825 A.2d 723, 726 (Pa. Commw. 2003) (emphasis added).

7. Admitted as a conclusion of -law to which no responsive pleading is required under the applicable Pennsylvania Rules of Civil Procedure. "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. 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." *Temple University v. Johanson*, 2001 Phila Ct. Com. PL LEXIS 71 (Phila. Com. P.

LEXIS, November 15, 2001, Decided.

8. Admitted as stated above.

9. Admitted as stated above.

A. No Allegations Against Generic Defendants in Plaintiffs' Third Amended Complaint Are Preempted by the Supremacy Clause of the United States Constitution

10. Admitted as stated. By way of further response, it is axiomatic that to determine whether a state law conflicts with federal law, the laws at issue must be identified. As Generic Defendants have not identified any state law that would purportedly conflict with federal law, there can be no finding of preemption. "Pre-emption analysis requires us to compare federal and state law." *Mensing* at 2573.

11. Denied. 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 made false and misleading statements and representations designed to encourage dangerous off-label use of metoclopramide. Also present in the prior iterations of Plaintiffs' complaint and their TAMLFC are allegations that Generic Defendants 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 the false statements, and that they failed to fulfill their obligations to properly test or inspect their product, review publicly available information identifying the serious problem posed by metoclopramide, or to fulfill their obligations to report all necessary information regarding their products to the appropriate administrative agencies. Likewise, Plaintiffs have consistently alleged that metoclopramide is unfit for long-term use, that 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 that Generic Defendants actively concealed and suppressed information identifying the danger posed by the drug and the frequency with which injuries occurred. The changes appearing in Plaintiffs' TAMLFC were made in order to eliminate allegations that the generic manufacturers should have changed the content of their metoclopramide labels, and to clarify and separate the claims alleged against both the Generic Defendants and the Brand Name Defendants. As the vast majority of the theories of liability pled in Plaintiffs' previous complaints were not considered by the *Mensing* Court, many allegations did not need to be altered or clarified.

12. Denied. As stated above and as is apparent from the portions of the TAMLFC quoted in Generic Defendants Preliminary Objections, there are numerous premises upon which Plaintiffs base the theories of liability appearing in their TAMLFC other than Generic Defendants' failure to warn of the risks of metoclopramide. These include, but are not limited to: (1) actively *misstating* the risks of metoclopramide use, (2) placing their metoclopramide on the market when the risks accompanying foreseeable use outweighed its utility; (3) failing to test, inspect, and monitor appropriate sources of information in order to identify dangers to consumers; (4) actively concealing from physicians and the consuming public the fact that metoclopramide should not be used for longer than 12 weeks; (5) accompanying their metoclopramide products with affirmations of fact which were relied upon by plaintiffs and their physicians, and to which their product failed to conform; and (6) creating a public health crisis through these negligent, intentional, wanton and/or reckless actions.

13. Denied. The statement to which Generic Defendants refer was made in the context of a discovery dispute over prior expert materials. Such materials are undoubtedly necessary in the context of a failure to warn claim, and the statement was intended to highlight

this fact. Defendants impermissibly seek to convert a single sentence appearing in a memorandum regarding unrelated issues into an admission that all of Plaintiffs' claims are preempted. Furthermore, Generic Defendants' argument is entirely misplaced in that preemption does not turn on the descriptive title or class of claims to which it belongs, but rather upon the duty placed on a defendant that gives rise to the claim. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 523 (1992).

14. Denied. Preemption does not serve to bar any "familiar subdivision of common law claims." *Id.* It is clear that the preemption found to exist in *Mensing* applies only to allegations that a generic manufacturer should have changed the content of their metoclopramide labels, e.g.:

> "[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 them 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. The claims appearing in Plaintiffs' TAMLFC are not preempted, as they do not allege that Generic Manufacturers should have changed the content of their label, which federal law prevented them from doing.

15. Admitted.

16. Admitted. By way of further response, "[w]hen addressing questions of express

or implied preemption, we begin our analysis 'with the assumption that the historic police powers of the States [are] not to be superceded by the Federal Act unless that was the clear and manifest purpose of Congress." *Altria Group, Inc. v. Good,* 129 S.Ct. 538, 543 (2008).

17. Admitted. By way of further response, "a State might nevertheless – at least in the absence of an express contrary command of Congress – confiscate or exclude from market [a product] which had complied with all the federal processing standards, 'because of a higher standard demanded by a state for its consumers.' A state regulation so purposed was, we affirmed, 'permissible under all authorities." *Florida Lime and Avocado Growers, Inc. v. Paul,* 83 S.Ct. 1210, 1218 (1963). "Congressional regulation at one end of the stream of commerce does not, ipso facto, oust all state regulation at the other end." *Id* at 1219.

18. Denied. Imposing liability upon Generic Manufacturers for introducing prescription drugs into the stream of commerce with labels containing false and misleading information, and without accompanying these drugs with adequate warnings and directions for safe use is entirely consistent with the Federal Food Drug and Cosmetic Act ("FDCA"). As noted by the Supreme Court, "[i]n 1906, Congress enacted its first significant public health law, the Federal Food and Drugs Act, ch. 3915, 34 Stat. 768. The Act, which prohibited the manufacture or interstate shipment of adulterated or misbranded drugs, supplemented the protection for consumers already provided by state regulation and common law liability." *Wyeth v. Levine,* 129 S.Ct. 1187, 1195 (2009). The FDCA still prohibits the introduction into interstate commerce of misbranded drugs, which include drugs with labels containing information that is "false or misleading" or which lack adequate warnings or directions for use. 21 U.S.C. §331(a); 21 USC §352(a),(f); *see also* Brief for the United States as *amicus curiae, PLIVA, Inc. v. Mensing,* 2011 WL 741927 at *3 (Mar. 2, 2011).

19. Denied. The allegations appearing in Plaintiffs' TAMLFC are not preempted as they do not allege that Generic Defendants should have taken any action prohibited by federal law. Defendants' bare assertion that the claims asserted by Plaintiffs are not viable under state law lacks any support and is also denied.

1. Plaintiffs Have Alleged that Generic Manufacturers Failed to Provide *Any* Warning to Consumers or Physicians, Not that They Have a Duty to Provide *Additional* Warnings

20. Denied. Plaintiffs' complaint does not allege that Generic Defendants should have communicated information in addition to or different than the information that appeared in the labeling for the brand name drug. Rather, Plaintiffs allege that Generic Defendants failed to communicate information that appeared in the drug's approved labeling to these individuals. Federal law does not preempt the duty of a generic manufacturer to actually *provide* warnings to physicians and patients – it only prevents them from providing warnings that "are not consistent with" the approved labeling of the drug. *Mensing* only speaks to the ability of a generic manufacturer to send "Dear Doctor Letters" with warnings that *are different or in addition to* the warnings appearing in the label for the brand name drug. *See* United States *amicus* Brief at pg. 18 ("To be sure, nothing in the FDCA or FDA's regulations categorically forbid 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."; *see also, Fisher v. Pelstring, et al.*, 4:09-cv-00252, Order dated 9/30/11 (D.S.C.), attached as Exhibit D; *Keck v. Endoscopy Center of Southern Nevada*, Case No. A57837, Order dated 8/19/2011, attached as Exhibit E; *Brasley-Thrash v. Teva Pharmaceuticals USA, Inc*., CA No. 10-00031 (S.D. Ala), Order dated 9/12/11, attached as Exhibit F (finding claims 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*).

21. Denied. As stated above, the *Mensing* Court only considered a "Dear Doctor" letter that included warnings "in addition to" those appearing in the labeling for the brand name drug, it did not consider whether a generic manufacturer could notify physicians of information appearing in the approved labeling of the drug through such means.

22. Denied. Generic Defendants' reliance on the Order of the District Court in *Mensing* is misplaced. The court issued its ruling without the benefit of the FDA's position as stated in the *amicus* brief filed by the United States in *Mensing.* As stated above, the FDA has stated that there is no prohibition on generic manufacturers unilaterally sending "Dear Doctor" letters, as long as those communications are "consistent with, and not contrary to" the approved labeling for the drug.

23. Denied. Again, Generic Defendants argument misunderstands Plaintiffs' allegations. Plaintiffs' contention that Generic Manufacturers should have communicated information appearing in the FDA approved labeling for the brand name drug relates to the fact that the drug was not to be used for longer than 12 weeks, not to the fact that their label contained false statements of risk. At the time the drug was approved, its label contained no statement prohibiting use of the drug for longer than 12 weeks. TAMLFC at ¶ 101. The last time that the information appearing in the label for metoclopramide was provided to Physicians prior to the 2009 label change was in 2002, the year the label was last published in the *Physician's Desk Reference. Id.* In 2003, information was added to the label regarding use of the drug in geriatric patients, and in 2004, statements were added in bold text stating that "**Therapy should not exceed 12 weeks in duration.**" *See Fisher* Order, Ex. D, at pg. 6. No Defendant in this litigation made any effort to see that these warnings were provided to the

medical community, either through dissemination of a "Dear Doctor" letter, publication of the label in the PDR, engagement in risk minimization management strategies involving communication with prescribers and patients, such as with a Medication Guide, or otherwise. There is no difficulty reconciling Plaintiffs' claims with the concept of duty and causation – a reasonable trier of fact could determine that a physician who received the warning containing the prohibition on long term use would have declined to prescribe the drug for longer periods, even though the labeling for the drug still contained false information understating the frequency at which side effects occurred. Likewise, if the Plaintiffs received a warning through a Medication Guide, or other risk minimization tools, stating that use should not exceed 12 weeks, Plaintiffs would have heeded that warning and declined to use the drug for longer.

24. Admitted. By way of further response, it is important to note that until 2007, the FDA itself lacked the authority to make changes to the labeling for an approved drug.

25. Denied. Plaintiffs' claims that Generic Defendants should have communicated the information appearing in the 2003 and 2004 labeling changes made to the FDA approved labeling for Reglan are not preempted by *Mensing.*

2. The Failure of Generic Defendants to Update Their Metoclopramide Labels Are Parallel Claims, and Constitute Negligence *per se*

26. Denied. Generic Defendants' failure to include instructions and warnings regarding use of the drug in geriatric patients and prohibiting the use of the drug for longer than 12 weeks are actionable as parallel claims for failure to warn. "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." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 444 (2005). Furthermore, evidence of non-compliance with federal regulations is proof of the Generic Manufacturer's breach of a standard of care under the doctrine of negligence *per se. See*

Fisher Order, Ex. D at pg. 41 ("For purposes of the plaintiffs' other causes of action, this ruling does not impact the plaintiffs' ability to argue, under the doctrine of negligence per se, that certain statutes and regulations establish the duty of care owed by PLIVA to the plaintiffs and that PLIVA breached that duty by violating said statutes and regulations").

27. It is admitted that the manufacture and sale of generic drugs are regulated by the Food and Drug Administration ("FDA") pursuant to authority granted by Congress in the Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

28. Admitted in part and denied in part. It is admitted that generic drugs must have the same active ingredient(s), the same route of administration, and the same labeling as their brand-name counterpart, and that these requirements apply as long as a generic drug is on the market. It is denied that these constitute the only "clinically significant" characteristics of a prescription drug. For instance, generic drugs are not required to use the same packaging as the brand-name drug, and the FDA has indicated that manufacturers may use specialized packaging as a means to minimize the risks of using their drug, such as risks posed by chronic off-label use. Guidance for Industry: Development and Use of Risk Minimization Action Plans (2005) ("RiskMAP Guidance"), attached hereto as Exhibit G.

29. Admitted. By way of further response Generic Manufacturers apparently concede that federal law prohibits the marketing of a drug with labeling that contains information that is false or misleading, or that lacks adequate warnings or instructions for use. As a result, any state law that "parallels" this requirement, i.e. prohibits the sale of the drug, would not be preempted. 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, 495

(1996).

30. Denied. "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 requirement 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." *Medtronic v. Lohr*, 518 U.S. at 495.

31. Denied. Generic Defendants' reliance on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), is misplaced. The *Buckman* Court considered "fraud-on-the-FDA" claims against a third-party consultant to the manufacturer whose product caused the injury, and who owed no traditional common-law duty to the plaintiff. The Court also found *field preemption*, not *impossibility preemption* to obtain the result in that case. The Court acknowledged that its ruling did not serve to preclude claims such as those asserted by Plaintiffs in this litigation:

> 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.

Buckman, 121 S.Ct. 1012, 1019-1020; *see also, Desiano v. Warner-Lambert Co.*, 467 F.3d 85 (2nd Cir. 2006); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 942-43 (8th Cir. 2011) (finding traditional common-law claims against manufacturers not preempted under *Buckman*).

3. <u>The Court's Analysis in *Mensing* is Significantly Different After the Passage of the FDAAA</u>

32. Denied. 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.

33. Denied. It is clear from the Court's decision in *Mensing* 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©(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.

With 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 addition of Black Box Warning to 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, 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*.

34. Admitted. Generic Defendants here acknowledge that it is only a "state law that would require them to [change their labeling]" that is preempted under *Mensing*. After passage of the 2007 Act, the ability to change the labeling for their drug no longer rested solely with their brand-name counterpart. Furthermore, the decision to change the labeling no longer depended on "uncertain federal agency and third-party decisions." Congress 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.

35. Admitted in part. The linchpin of *Mensing's* analysis is that neither the Generic Defendants *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. Generic Defendants assertion that it is the CBE provision that is the hallmark of the decision also belies the fallacy in their argument regarding the failure of Generic Manufacturers 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.

36. Denied. Preemption does not serve to preclude "any familiar subdivision of common-law claims" *Cipollone,* 505 U.S. at 523. Rather, a court "must look to each of petitioner's common law claims to determine whether it is in fact preempted." *Id.* The preemption announced by the Court in *Mensing* precludes only claims asserting that "generic manufacturers may change their labels after initial FDA approval." *Mensing*, 131 S.Ct. at 2574.

37. Denied for those reasons stated above.

4. Both State and Federal Law Prohibited Generic Manufacturers From Selling Their Metoclopramide Products With Labels Containing False and Misleading Information, and Which Lacked Adequate Warnings and Instructions for Use

38. Denied. While selling a product that is known to lack adequate warnings and instructions for safe use does subject Generic Defendants to liability for placing an unreasonably dangerous products into the hands of consumers, that is not the sole allegation in Plaintiffs' TAMLFC. It is also alleged that Generic Defendants made false misrepresentations regarding the safety of the products which they knew were being relied upon by physicians in deciding to prescribe the drug for longer than 12 weeks. Plaintiffs' TAMLFC also alleges that Defendants were aware that their metoclopramide products were being used in situations never considered by the FDA in granting approval for the drug, and that this use was causing serious injury to a significant number of people. Taking these allegations as true, Plaintiffs have stated facts sufficient to support all of the causes of action stated within the TAMLFC, and Generic Defendants persistence in attempting to convince the Court that Plaintiffs' have only alleged

"failure-to-warn" claims is disingenuous at best.

39. Denied. 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).

40. Denied. 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). As was clearly stated by the Court in *Mensing*, the issue of whether generic manufacturers could comply with its duties under state law by ceasing to sell its metoclopramide products was not considered in rendering its decision. The denial of the petition for rehearing does not lend any support to Generic Defendants' argument. Furthermore, as shown above, the only claim considered in *Mensing* was that the generic manufacturer should have changed the content of their 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.

41. Denied. *Mensing* held that a generic manufacturer cannot change the content of its label, not that it could not be held liable for its products warnings. The question of whether a product's label constitutes a warning is a question of fact to be determined by the jury. *Borel v. Fibreboard Paper Products Corp.*, 493 F.2d 1076, 1105 (5th Cir. 1973).

42. Denied. "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. *Medtronic v. Lohr*, 518 U.S. 470(1996); *Bates v. Dow Agrosciences*, 544 U.S. 431 (2005); *Riegel v. Medtronic*, 552 U.S. 312 (2008);

> 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..

43. Denied. "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.").

44. Admitted. By way of further response, "[y]et through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged … with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 129 S.Ct at 1197-1198.

45. Denied. Generic Defendants' argument that allowing juries to determine whether a drug was misbranded, and therefore whether they should be held liable for introducing the dangerous product into the marketplace was clearly not before the Court in *Mensing*. *Mensing* considered a single type of preemption (impossibility) regarding a single claim (that a generic manufacturer should have changed the content of their label), it did not find that the type of preemption asserted by Generic Defendants here (frustration of purposes) would preclude any of Plaintiffs' claims.

46. Denied. Generic Defendant's argument only considers one portion of the justification for the passage of the Hatch-Waxman amendments. As is clear from the title of the law passed by Congress (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 misrepresented and concealed the fact that their drug was dangerous and ineffective. Clearly, this is not the scheme envisioned by Congress.

47. Denied. Federal and State law both prohibit Generic Manufacturers from engaging in those actions alleged by Plaintiffs. Plaintiffs' claims are not preempted under *Mensing*, and only further the goals of Congress in passing the FDCA and the Hatch-Waxman Amendments.

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

48. Denied. Generic Defendants point to no federal statute, regulation or other requirement that would prevent them from approaching the brand-name manufacturer to remove false information or add safer warnings to the label for metoclopramide. For the preemption found by the Court to preclude such a claim, it would have to be "physically impossible" for Generic Defendants to take such action. As there was no such prohibition, these claims are not preempted.

49. Admitted as stated. By way of further response, the state law duty at issue in *Mensing* was the duty to change the content of the labeling for their metoclopramide products.

Going to either the FDA or the brand-name manufacturer would not have satisfied a duty to change the content of Generic Manufacturer's label, but it could have satisfied their state law duty *to exercise reasonable* care in the manufacture, marketing and sale of their metoclopramide products. Such a state duty was not before the Court in *Mensing*, and defendants have identified no provision of federal law that would prevent them from unilaterally approaching the NDA holder in order to make appropriate changes.

50. Admitted as stated. 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 Manufacturers duty to exercise reasonable care in the production, marketing and sale of metoclopramide. 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.

51. Admitted as stated. If Plaintiffs claims were based on the assertion that the Generic Defendants were required to change the content of their labeling, such claim would be preempted under *Mensing*, as they would not unilaterally be able to take such action. As Plaintiffs' TAMLFC makes no allegation, however, the issue is entirely irrelevant to the issues to be decided by the Court. Plaintiffs' allege that Generic Defendants' failure to take any action was unreasonable in light of their federal and state law duties. 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.

52. Denied. Generic Defendants' failure to approach the NDA holder about the significant safety hazard posed by their drug products 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

53. Denied. 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.

54. Denied. Generic Defendants do not define the phrase "non-specific defect" and it is therefore unknown what type of defect to which this objection refers. As stated above, the *Mensing* decision speaks only to a law requiring a manufacturer to change the content of the labeling for its product and does not speak to design defects. State laws that "require manufacturers to design reasonably safe products … plainly do not qualify as requirements for labeling…" *Bates*, 125 S.Ct. at 1798.

55. Denied. 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.

56. Admitted. By way of further response, 21 U.S.C. § 355(j) 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)."

57. Admitted. As stated above, the FDA is not authorized to subject any aspect of a generic drug's design to be the "same as" the brand-name drug, other than those listed.

58. Admitted as stated. By way of further response, nothing in the FDCA or Hatch-Waxman amendments required Generic Manufacturers 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.

59. Denied as stated. While the FDCA requires that a generic drug be the "same as" the reference listed drug ("RLD") in many respects, they are not required to be identical in all respects to the RLD. To the extent that the design of a prescription drug includes packaging, or other aspects of the design not subject to the "sameness" requirement off 21 U.S.C. 355(j), Generic Defendants have no requirements that differ from those placed on the brand-name drug.

60. Admitted. By way of further response, 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 serve to preempt claims based upon any other actions that could have been taken by the Generic Defendants.

61. Denied. State law rules governing the design of a product are not preempted,

because they do not require a generic manufacturer to differ their product from that of the brand name drug in active ingredients, route of administration, dosage from, strength, or labeling. *See Bates v. Dow Agrosciences LLC*, 125 S.Ct. at 1798.

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

62. Denied. Generic Defendants have failed to point to a single requirement of federal law that would have prevented Generic Defendants 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 take such action. As a result, all of Plaintiffs claims appearing in the TAMLFC are unaffected by the Supreme Court's decision in *Mensing.*

63. Denied. 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 long-term use,

(7) that 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) that 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.

64. Denied. The only claims barred by the Supreme Court's decision in *Mensing* are those where it is alleged that a generic manufacturer should have changed the content of its warning to differ from that of the brand name drug.

COUNT I – STRICT LIABILITY

65. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

66. Admitted. Defendants acknowledge that Count I of their TAMLFC contains the allegations stated.

67. Denied. While many of the claims contained in Count I of Plaintiffs' TAMLFC are substantially similar to those appearing in previous versions of the complaint, that is irrelevant to the matter before the Court. 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.

68. Denied. 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." *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."

69. Denied. The Supreme Court decided that a generic manufacturer could not unilaterally change the content of its labeling, and that they could therefore not be held liable under a state-law requirement that they take such action. Furthermore, the failure to *give* adequate warnings of a product's dangers can render the product unreasonably dangerous. Restatement (Second) of Torts §402(A), comment k. Furthermore, a seller's warning must be reasonably calculated to reach those to whom it is directed, and the presence of an intermediate party will not by itself relieve the seller of this duty. *Borel,* 493 F.2d at 1091; *Sterling Drug Co.*

v. Cornish, 370 F.2d 82 (8th Cir. 1966); Noel, Products Defective Because of Inadequate Directions or Warnings, 23 S.W.L.J. 256 (1916).

70. Denied. Neither federal law nor state law required the generic manufacturers to sell metoclopramide, and Generic Defendants could have 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 renders them liable.

71. Denied. *Mensing* states that Generic Defendants could not provide warnings that were different or in addition to those warnings that appeared in the labeling for the brand-name drug. It is silent as to the duty and ability of a generic manufacturer to communicate *existing* warnings to the medical community, or to alert individuals to important safety related labeling changes made to the brand-names label, and approved by the FDA.

72. Denied. 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 is sufficient. This would be so even though the labeling also contained false statements that underestimated the risk of side effects.

73. Denied. Generic Defendants cite to no provision of federal law that would have

prevented them from ceasing sales of their drug if they determined that their metoclopramide products were unreasonably dangerous. Furthermore, Generic Defendants make no citation to any state law which they believe Plaintiffs' allegations are insufficient to prove. As a result there is no merit to their argument.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' strict liability claims.

COUNT II – STRICT LIABILITY – DESIGN DEFECT

74. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

75. Admitted. Defendants acknowledge that Count II of their TAMLFC contains the allegation quoted.

76. Denied. *Mensing* did not consider strict liability design defect claims, only claims that generic manufacturers should have unilaterally changed the content of their labels for metoclopramide.

77. Denied. Generic Defendants cite no support for their assertion that Plaintiffs' cannot prevail as a matter of law on their claims of strict liability for design defect. As shown above, Plaintiffs must show that it was unreasonable to sell their metoclopramide products as designed, due to the dangers posed by the drug. Plaintiffs' TAMLFC contains sufficient factual allegations to enable a reasonable trier of fact to reach this conclusion.

78. Denied. Defendants design defect claims are not based solely on the fact that Generic Defendants' metoclopramide products lacked adequate warnings. Furthermore, *Mensing* considered only 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.

79. Denied. 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.

80. Denied. As Generic Defendants have not indicated any law that would require Plaintiff's to show the existence of a feasible alternative design, such is unnecessary in order to prevail on a claim of strict liability for design defect. Furthermore, as acknowledged by Generic Defendants, the only aspect 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.

81. Denied. As stated above in response to Generic Defendants' Preliminary Objection # 39, the *Mensing* court explicitly acknowledged that such claims were not before them:

> 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).

82. Denied. Generic Defendants cite no provision of federal law that would prevent them from ceasing sales of their drug if they determined that their metoclopramide products were unreasonably dangerous, or altering the design of its product to reduce the risks posed by its drug through specialized packaging. Furthermore, Generic Defendants make no citation to any state law which they believe Plaintiffs' allegations are insufficient to prove. As a result there is no merit to their argument.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' strict liability design defect claims.

COUNT III – NEGLIGENCE

83. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

84. Admitted. Defendants acknowledge that Count II of their TAMLFC contains the allegation stated. By way of further response, Count II in Plaintiffs' TAMLFC also alleges that Generic Defendants were negligent in their research, development, testing, study, manufacture and sale of their metoclopramide

85. Denied. *Mensing* did not consider claims that a manufacturer failed to exercise reasonable care in their various actions relating to the research, testing, manufacture, sale and promotion of metoclopramide. The Court only considered the claim that the generic manufacturers should have unilaterally changed the content of their labels for metoclopramide.

86. Denied. Defendants cite no support for their assertion that Plaintiffs' cannot prevail as a matter of law on their claims for negligence. Plaintiffs' TAMLFC alleges that

Generic Manufacturers owed Plaintiffs a duty in all of their several undertakings to exercise reasonable care so as not to cause harm. Plaintiffs have further alleged that Generic Defendants breached their duty to exercise reasonable care, and that their breach resulted in physical injury to Plaintiffs. Plaintiffs have also alleged that Generic Defendants breached the standard of care placed upon them by violation of federal laws designed to protect the health and safety of consumers.

87. Denied. The *Mensing* Court considered only the claim that generic manufacturers should have unilaterally changed the content of their labels for metoclopramide. Plaintiffs do not assert such claims in their TAMLFC. The *Mensing* Court likewise did not consider whether a state law duty requiring a manufacturer to suspend sales of its drug was preempted by federal law. Generic Defendants have cited to no federal law that would prevent them from ceasing to sell the drug if they learn that their product is causing harm to individuals in the marketplace. To the contrary such a state law duty is entirely consistent with and parallels federal requirements that prohibit Generic Manufacturers from introducing their metoclopramide into interstate commerce if their labeling contains statements that or false or misleading, or lack adequate warnings or instructions for use.

88. Denied. The *Mensing* Court and the Brief for the United States as *amicus curiae* acknowledge that the argument that the generic manufacturers should have stopped selling the drug were not advanced by Plaintiffs to the Supreme Court. Furthermore, a denial of a petition for rehearing has no precedential value, and says nothing about the merits of the arguments contained within.

89. Denied. 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 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.

90. Admitted. Plaintiffs admit that they have no private right of action under the FDCA. This fact is entirely irrelevant as a state laws that parallel the requirements of federal law are not preempted. Furthermore, this fact does not affect the doctrine of negligence *per se* which provides that the standard of care expected of a reasonable generic drug manufacturer is defined, in part, by those federal regulations which govern their conduct. Violation of a federal statute or regulation is therefore proof that the Generic Manufacturers were negligent as a matter of law.

91. Denied. 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, failed to alert physicians and consumers to 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.* Generic Defendants cite to no provision of federal law that would have prevented them from taking such action, and make no citation to any state law which they believe Plaintiffs' allegations are insufficient to prove. As a result their argument lacks merit.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' negligence claims.

COUNT IV – NEGLIGENCE *PER SE*

92. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

93. Admitted. Defendants acknowledge that Count II of their TAMLFC contains the allegation stated.

94. Denied. *Mensing* did not consider claims such as those presented in Count IV of Plaintiffs' TAMLFC, the Court only considered the claim that the generic manufacturers should have unilaterally changed the content of their labels for metoclopramide.

95. Denied. Defendants cite no support for their assertion that Plaintiffs' cannot prevail as a matter of law on their claims for negligence *per se*. Such 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.

96. Denied. While certain claims appearing in this count pertain to labeling and misbranding, other claims do not, such as the failure of Generic Manufacturers to comply with requirements regarding pharmacovigilance duties and monitoring the medical and scientific literature.

97. Denied. 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 that obliged them to stop selling the product.

98. Denied. 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 are not within the exclusive province of the federal government.

99. Denied. 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.

100. Denied. Plaintiffs' negligence *per se* claims are based on the traditional state law duty that requires manufacturers to exercise reasonable care in the production, marketing and sale of their products. Individuals may sue to enforce provisions of federal law through a state law that parallels the requirements of the federal government.

101. Denied. Plaintiffs' have alleged that Generic Defendants violated numerous federal and state law provisions designed and enacted for the purpose of protecting the health and safety of prescription drug consumers. Generic Defendants violations of applicable statutory and regulatory provisions prove their negligence as a matter of law.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' negligence *per se* claims.

COUNT V – FRAUD, MISREPRESENTATION AND SUPPRESSION

102. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

103. Admitted. Defendants acknowledge that Count V of their TAMLFC contains the

allegation stated. By way of further response, Plaintiffs' TAMLFC also alleges that Generic Defendants actively engaged in fraud, misrepresentation and suppression by withholding and suppressing evidence of fraud.

104. Denied. *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.

105. Denied. Defendants cite no support for their assertion that Plaintiffs' cannot prevail as a matter of law on their claims for misrepresentation, fraud and suppression. 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.

106. Denied. See above. Even if Generic Defendants were actually unaware that the

brand defendants submitted false information in support of their application to market Reglan, the information showing these facts was readily available to Generic Defendants, yet they willfully chose to remain ignorant of those facts.

107. Denied. 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. Had Generic Defendants withdrawn their metoclopramide from the market prior to making such statements, they would not have violated any provision of federal law.

108. Denied. Plaintiffs' do not allege that Generic Defendants should have "corrected" fraudulent statements made by others, but rather that they should have refrained from actively participating in the fraud by distributing their metoclopramide products into the stream of commerce with the very same false and fraudulent statements.

109. Denied. 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.

110. Denied. 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.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' misrepresentation, fraud and suppression claims.

COUNT VI – CONSTRUCTIVE FRAUD

111. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

112. Admitted. Defendants acknowledge that Count V of their TAMLFC contains the allegation stated.

113. Denied. *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.

114. Denied. Defendants cite no support for their assertion that Plaintiffs' cannot prevail as a matter of law on their claim for constructive fraud. 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.

115. Denied. Just as *Mensing* was silent regarding claims of misrepresentation, fraud and suppression against a generic manufacturer, they were equally silent regarding claims of constructive fraud.

116. Denied. Plaintiffs' have sufficiently alleged that Generic Defendants engaged in actions that constitute constructive fraud. 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 constructive fraud, and have therefore failed to show that they are entitled to dismissal of these claims.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' misrepresentation, fraud and suppression claims.

COUNT VII - BREACH OF EXPRESS AND IMPLIED WARRANTIES

117. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

118. Denied. Plaintiffs admit that their claims for breach of express warranty are based on affirmations of fact that appeared in the labeling for metoclopramide to which Generic Defendants' products failed to conform. Plaintiffs' claims for breach of implied warranties are not based on any aspect of the labeling for metoclopramide, but rather on the fact that the metoclopramide manufactured and sold by Generic Defendants was not merchantable, and was

not fit for the purposes for which it was sold.

119. Denied. *Mensing* did not consider claims for breach of either express or implied warranties such as those appearing in Count VII of Plaintiffs' TAMLFC, the Court only considered the claim that the generic manufacturers should have unilaterally changed the content of their labels for metoclopramide.

120. Denied. Defendants cite no support for their assertion that Plaintiffs' cannot prevail as a matter of law on their claim for breach of express and implied warranties. Plaintiffs' TAMLFC alleges facts sufficient to prove that Defendants breached both express warranties given regarding their products, and that the metoclopramide manufactured and sold by Generic Defendants was unmerchantable and was not fit for the purpose for which it was sold.

121. Denied. 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.[2] 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

[2] 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.

> 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."

Bates, 544 U.S. at 445. Like the express warranty claims discussed in *Bates*, Plaintiffs' implied warranty claims likewise are the result of "a contractual commitment voluntarily undertaken," and would not be preempted for precisely the same reason.

122. Denied. Plaintiffs' TAMLFC contains allegations that Generic Defendants made representations other than those appearing in labeling. To the extent that Generic Defendants intended their statement to read that Plaintiffs' make no allegation that Generic Defendants provided any express warranty other than those contained in labeling, such statement is admitted.

123. Denied. Plaintiffs' breach of implied warranty claims are not based on labeling, but rather that the metoclopramide manufactured and sold by Generic Defendants was non-merchantable and unfit for the purposes for which it was sold. These claims are not preempted.

124. Denied. 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. Eli Lilly & Co.*, 768 F.2d 93 (6th Cir. 1985); *Parke, Davis & Co., v. Stromsodt,*

411 F.2d 1390 (8th Cir. 1969).[3]

125. Denied. 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 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 longer than 12 weeks. 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.

126. Denied. Plaintiffs' have sufficiently alleged facts supporting claims for breach of express and implied warranties. Generic Defendants have identified no federal law that required them to sell their metoclopramide products for uses to which it was not suited. To the contrary, federal law prohibited the sale of metoclopramide when their labels contained false statements or affirmations of fact. Furthermore, the duties imposed upon manufacturers by breach of warranty claims are not imposed by operation of state law, but by the manufacturers themselves in willfully marketing and selling the drug with information they knew to be false in their labeling. In addition, Generic Defendants have identified no state law under which Plaintiffs factual allegations would be insufficient to prove claims for breach of express and implied warranties, and have therefore failed to show that they are entitled to dismissal of these claims.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' breach of warranty claims.

[3] 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).

COUNT VIII – UNFAIR AND DECEPTIVE TRADE PRACTICES

127. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

128. Admitted. By way of further answer, Plaintiffs TAMLFC also alleges that Generic Defendants engaged in efforts to promote the use of metoclopramide in order to increase demand for the drug so that they may benefit financially. *See* TAMLFC, Ex. B, ¶200. Plaintiffs further allege that Generic Defendants influenced the decisions of prescribing physicians and consumers in order to increase or maintain the sales of their drugs and promoted their metoclopramide without conducting sufficient pre-clinical, clinical, and post-approval testing and without performing adequate post-marketing surveillance and analyses of the drug. *Id* at ¶¶ 200-201.

129. Denied. *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 warnings.'" 129 S.Ct at 547.

130. Denied. Defendants cite no support for their assertion that Plaintiffs' cannot prevail as a matter of law on their claim that Generic Defendants' engaged in unfair and deceptive trade practices. These claims are not preempted by the Supreme Court's decision in *Mensing*, and Generic Defendants have identified no state law under which they would be unable to recover under the facts alleged.

131. Denied. *Mensing* considered only the claim that a generic manufacturer should have changed the content of their labeling for metoclopramide in order to provide warnings that were different or in addition to those warnings appearing in the label for the brand name drug. The decision did not provide any analysis relevant to claims against a generic defendant for engaging in unfair and deceptive trade practices.

132. Denied. Plaintiffs' TAMLFC does not allege that Generic Defendants should have "corrected" any unfair or deceptive trade practices of a different company. Rather, 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.

133. Denied. *Mensing* does not state that Generic Defendants are entitled to immunity from liability for knowingly and willfully inducing consumers to engage in highly dangerous long-term usage of metoclopramide through misrepresentation and fraud. *Mensing* states that a generic manufacturer cannot be held liable for failing to provide warnings that are different or in

addition to those appearing in the labeling for the brand-name drug.

134. Denied. Plaintiffs' have sufficiently alleged facts supporting claims against Generic Defendants for Unfair and Deceptive Trade Practices. Generic Defendants have identified no federal law that required them to sell their metoclopramide products for uses to which it was not suited, or based on representations that were untrue. To the contrary, federal law prohibited the sale of metoclopramide with labels containing false statements or inadequate warnings or instructions for use. In addition, Generic Defendants have identified no state law under which Plaintiffs factual allegations would be insufficient to prove claims for engaging in unlawful and deceptive trade practices, and have therefore failed to show that they are entitled to dismissal of these claims.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' unfair and deceptive trade practices claims.

COUNT IX - UNJUST ENRICHMENT

135. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

136. Admitted. By way of further answer, Plaintiffs TAMLFC also alleges that Generic Defendants accepted and retained profits from sales of metoclopramide with knowledge that the drug was being sold for use in situations where it was not beneficial, and which were highly likely to result in serious personal injury to those who purchased the product. *See* TAMLFC, Ex. B, ¶208. Plaintiffs further allege that Generic Defendants knowingly derived profit as the result of misrepresentations by Generic Defendants and knowing that Plaintiffs relied on these representations in deciding to purchase and consume Generic Defendants' products. *Id.*

137. Denied. *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.

138. Denied. Defendants cite no support for their assertion that Plaintiffs' cannot prevail as a matter of law on their claim that Generic Defendants' were unjustly enriched at Plaintiffs' expense through their sales of metoclopramide. These claims are not preempted by the Supreme Court's decision in *Mensing,* and Generic Defendants have identified no state law under which they would be unable to recover under the facts alleged.

139. Denied. As stated above, 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. TAMLFC, Ex. B, ¶ 207. Generic Defendants are liable to Plaintiffs for the profits they received from these actions.

140. Denied. 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 or effective for the uses to which it was being put. Absent such a showing, Plaintiffs' unjust enrichment claims are not preempted.

141. Denied. Plaintiffs' have sufficiently alleged facts supporting claims against Generic Defendants for unjust enrichment. Generic Defendants have identified no federal law

that required them to sell their metoclopramide products for uses to which it was not suited, or based on representations that were untrue. To the contrary, federal law prohibited the sale of metoclopramide with labels containing false statements or inadequate warnings or instructions for use. In addition, Generic Defendants have identified no state law under which Plaintiffs factual allegations would be insufficient to prove claims for unjust enrichment, and have therefore failed to show that they are entitled to dismissal of these claims.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' unjust enrichment claims.

COUNT X – CONSCIOUS OR NEGLIGENT MISREPRESENTATION INVOLVING PHYSICAL HARM

142. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

143. Admitted.

144. Admitted.

COUNT XI – CIVIL CONSPIRACY

145. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

146. Admitted. By way of further response, Plaintiffs TAMLFC also 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. *See* TAMLFC, Ex. B, ¶224.

147. Denied. *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.

148. Denied. Generic Defendants cite no support for their assertion that Plaintiffs' cannot prevail as a matter of law on their claim that Generic Defendants' were engaged in a civil conspiracy to violate provisions of state and federal law in order to conceal important safety information from the medical community in order to maintain their profits from metoclopramide sales. These claims are not preempted by the Supreme Court's decision in *Mensing*, and Generic Defendants have identified no state law under which Plaintiffs would be unable to recover under the facts alleged.

149. Denied. 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.

150. Denied. Plaintiffs' have sufficiently alleged facts supporting claims against Generic Defendants for civil conspiracy. Generic Defendants have identified no conflict between federal law and state law that would preempt such claims. To the contrary, federal law prohibited the precise activities upon which Plaintiffs' civil conspiracy claim is based. In addition, Generic Defendants have identified no state law under which Plaintiffs' factual

allegations would be insufficient to prove claims for civil conspiracy, and have therefore failed to show that they are entitled to dismissal of these claims.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' civil conspiracy claims.

COUNT XII – LOSS OF CONSORTIUM

151. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

152. Denied. Generic Defendants cite no support for their assertion that Plaintiffs cannot prevail as a matter of law on their loss of consortium claims.

153. Admitted.

154. Denied. Generic Defendants have not identified any provision of federal law that would preempt any of the claims alleged in Plaintiffs' TAMLFC. The only provision of federal law relied upon by Generic Defendants is the requirement that the active ingredients, dosage form, route of administration, strength and labeling of a generic drug must be the "same as" their brand name counterpart. *Mensing* states that this provision of federal law preempts a claim that a generic manufacturer should have changed the content of its labeling in order to provide different or additional warnings to those appearing in the brand-name drug's label. Plaintiffs' TAMLFC contains no such allegation, and as a result, all of the causes of action asserted therein remain viable, as they are based upon theories of liability that in no way conflict with federal law. As the underlying claims are not preempted, Plaintiffs' loss of consortium claims likewise remain viable.

155. Denied. Plaintiffs' have sufficiently alleged facts supporting claims against Generic Defendants for loss of consortium. Generic Defendants have identified no conflict

between federal law and state law that would preempt such claims. In addition, Generic Defendants have identified no state law under which Plaintiffs' factual allegations would be insufficient to prove claims for loss of consortium, and have therefore failed to show that they are entitled to dismissal of these claims.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' loss of consortium claims.

COUNT XIII – WRONGFUL DEATH

156. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

157. Denied. Generic Defendants cite no support for their assertion that Plaintiffs cannot prevail as a matter of law on their wrongful death claims.

158. Admitted.

159. Denied. Generic Defendants have not identified any provision of federal law that would preempt any of the claims alleged in Plaintiffs' TAMLFC. The only provision of federal law relied upon by Generic Defendants is the requirement that the active ingredients, dosage form, route of administration, strength and labeling of a generic drug must be the "same as" their brand name counterpart. *Mensing* states that this provision of federal law preempts a claim that a generic manufacturer should have changed the content of its labeling in order to provide different or additional warnings to those appearing in the brand-name drug's label. Plaintiffs' TAMLFC contains no such allegation, and as a result, all of the causes of action asserted therein remain viable, as they are based upon theories of liability that in no way conflict with federal law. As the underlying claims are not preempted, Plaintiffs' wrongful death claims likewise remain viable.

160. Denied. Plaintiffs' have sufficiently alleged facts supporting claims against Generic Defendants for loss of consortium. Generic Defendants have identified no conflict between federal law and state law that would preempt such claims. In addition, Generic Defendants have identified no state law under which Plaintiffs' factual allegations would be insufficient to prove claims for wrongful death, and have therefore failed to show that they are entitled to dismissal of these claims.

WHEREFORE, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' wrongful death claims.

COUNT XIV – SURVIVAL ACTION

161. Plaintiffs acknowledge that Generic Defendants incorporate by reference the preceding paragraphs as if they were fully set forth in this section.

162. Denied. Generic Defendants cite no support for their assertion that Plaintiffs cannot prevail as a matter of law on their wrongful death claims.

163. Admitted.

164. Denied. Generic Defendants have not identified any provision of federal law that would preempt any of the claims alleged in Plaintiffs' TAMLFC. The only provision of federal law relied upon by Generic Defendants is the requirement that the active ingredients, dosage form, route of administration, strength and labeling of a generic drug must be the "same as" their brand name counterpart. *Mensing* states that this provision of federal law preempts a claim that a generic manufacturer should have changed the content of its labeling in order to provide different or additional warnings to those appearing in the brand-name drug's label. Plaintiffs' TAMLFC contains no such allegation, and as a result, all of the causes of action asserted therein remain viable, as they are based upon theories of liability that in no way conflict with federal law. As

the underlying claims are not preempted, Plaintiffs' survival action claims likewise remain viable.

160. Denied. Plaintiffs' have sufficiently alleged facts supporting claims against Generic Defendants for a survival action. Generic Defendants have identified no conflict between federal law and state law that would preempt such claims. In addition, Generic Defendants have identified no state law under which Plaintiffs' factual allegations would be insufficient to prove claims for a survival action, and have therefore failed to show that they are entitled to dismissal of these claims.

WHEREFORE, for the reasons stated above, Plaintiffs respectfully request that this Court DENY Generic Defendants' Preliminary Objections to Plaintiffs' Third Amended Master Long Form Complaint in their entirety.

Respectfully submitted,

PLAINTIFFS' LIAISON COMMITTEE

BY: /s/ Rosemary Pinto
Raymond J. Peppelman, Jr.
Stuart Eisenberg
Rosemary Pinto

VERIFICATION

I, Rosemary Pinto, verify that I am the attorney for the Plaintiffs and that the facts contained within this Response are true and correct to the best of my knowledge, information, and belief. I understand that this Verification is made subject to the penalties of 18 Pa. Cons. Stat. Ann. §4904 relating to unsworn falsification to authorities.

s/ Rosemary Pinto
Rosemary Pinto

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Response to Generic Defendants' Master Preliminary Objections to Plaintiffs' Third Amended Master Long Form Complaint was filed electronically with the Court and/or sent by first-class, U.S. mail, postage prepaid, to all parties in the above captioned matter and/or their counsel of record.

s/ Rosemary Pinto
Rosemary Pinto

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IN RE	:	
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REGLAN/METOCLOPRAMIDE	:	PHILADELPHIA COUNTY
LITIGATION	:	
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This Document Relates to All Cases	:	
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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

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