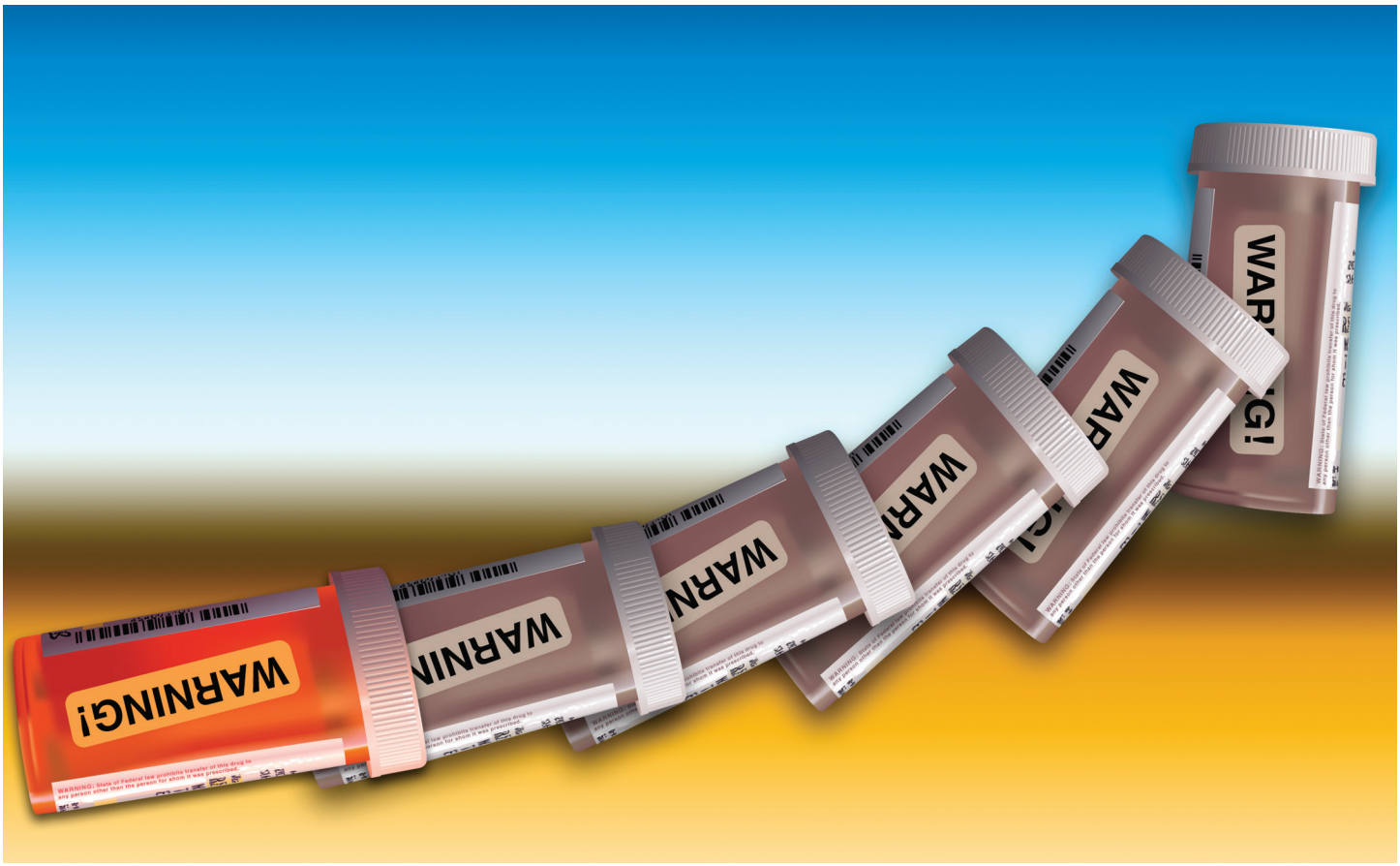
The State of Failure to Warn Claims Against Generic Drug Manufacturers

By M. Gabrielle Hils

Pliva, Inc. v. Mensing One Year Later



Pliva, Inc. v. Mensing, 131 S. Ct. 2567 (2011), the seminal United States Supreme Court case on federal conflict preemption for generic drug makers, is now one year old. Since the *Mensing* opinion was issued in June of 2011, many courts have addressed whether state law failure to warn claims against generic drug manufacturers may still proceed. In most instances, the issue has been decided in favor of the generic drug manufacturers, but plaintiffs continue their efforts to navigate around the Supreme Court's decision. This article contains a procedural history of the *Mensing* case, a summary of *Mensing*'s holdings, and a survey of the cases decided since *Mensing*, with a focus on the arguments asserted by plaintiffs to avoid dismissal of their state law product liability claims.

Federal Regulation of Prescription Drugs

In order to understand the holding in *Pliva, Inc. v. Mensing*, it is necessary to have a basic understanding of the federal regulation of prescription drugs. Before marketing a new prescription drug, a manufacturer must first obtain approval from the Food and Drug Administration (FDA). Approval is obtained though the submission of a New Drug Application, or NDA. 21 U.S.C. §355(a)–(b). The NDA contains information about the drug's safety and efficacy based on clinical trials, as well as proposed labeling addressing the appropriate use, warnings, precautions, and adverse reactions relating to the medication. 21 C.F.R. §201.56.

In 1984, Congress passed the Drug Price Competition and Patent Term Restora-

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tion Act, which amended the Food, Drug and Cosmetic Act to allow generic drugs to be brought to market more expeditiously upon the expiration of patents on branded drugs. These amendments are commonly referred to as the Hatch-Waxman amendments. Pursuant to these amendments, a generic drug manufacturer may submit an abbreviated new drug application, or ANDA. 21 U.S.C. §355(j). The generic manufacturer must demonstrate in its ANDA that the generic drug's active ingredient, route of administration, dosage, form, strength, and labeling are the same as that of the listed drug. *Id.*

The generic drug manufacturer is not required to conduct clinical trials. The FDA instead relies upon the safety data contained in the NDA of the listed drug. As explained in one of the committee reports on the Hatch-Waxman amendments, the focus is to "provide the Food and Drug Administration with sufficient information to assure that the generic drug is the same as the listed drug that has previously been determined to be safe and effective." H.R. Rep. No. 98-857, pt. 1, at 21 (1984), quoted in *Bartlett v. Mutual Pharm. Co., Inc.*, 659 F. Supp. 2d 279 (D. N. H. 2009) (containing a detailed explanation of the legislative history and regulation of prescription drugs by the FDA). As a result, brand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's. *Pliva, Inc. v. Mensing*, 131 S. Ct. at 2574 (citations omitted).

Pliva, Inc. v. Mensing—Lower Court Procedural History

Pliva, Inc. v. Mensing involved an appeal by two plaintiffs, Gladys Mensing and Julie Demahy. In 2001, plaintiff Gladys Mensing was prescribed the brand-name drug Reglan for the treatment of diabetic gastroparesis. *Mensing v. Wyeth, Inc.*, 2008 U.S. Dist. LEXIS 89365, *2 (D. Minn. Oct. 30, 2008). Her pharmacist filled the prescription with metoclopramide (MCP), the generic equivalent of Reglan. *Id.* at *4. Mensing alleged that she developed a neurological disorder known as tardive dyskinesia from her long term use of MCP. She sued the makers of Reglan and MCP under Minnesota law based on failure to warn theories. She alleged that none of the makers of MCP had taken steps to change the drug's warning label to disclose accurately the true risk of developing tardive dyskinesia from long term use of the drug. Although she had never ingested Reglan, Mensing also sued the makers of Reglan, asserting negligent misrepresentation, misrepresentation by omission, fraud by concealment, and constructive fraud claims against them for allegedly misstating the true risks associated with ingesting MCP. *Id.* at *10. She argued that the brand-name drug makers had "a legal duty to be truthful in their representations to the public about [their] brand-name products even if the aggrieved member of the public is not injured by those products" and that it was foreseeable that a generic drug manufacturer, in formulating the warnings for a generic drug, must or would rely upon the warnings contained in the brand-name drug manufacturer's labeling. *Id.* at *11, *15–16.

> Since the Supreme Court's decision in *Mensing*… [t]he plaintiffs' difficulty has been in pleading theories of recovery that are not premised upon state law failure to warn doctrines.

In response to the defendants' dispositive motions, the district court dismissed the plaintiff's claims against the generic drug defendants on federal preemption grounds, concluding that "under the federal statutory scheme, the labeling for generic drugs must always remain the same as that of the name brand drug, and that a generic drug manufacturer cannot unilaterally change its label without prior approval from the Food and Drug Administration.… [B]ecause Plaintiff's failure to warn claims relied on state law imposing a duty on the generic drug manufacturers, these claims directly conflicted with, and stood as an obstacle to the execution of, federal law." *Id.* at *3 (parentheticals omitted). The court also dismissed the plaintiff's claims against the brand-name drug defendants because the plaintiff had not taken their product and under Minnesota law the brand-name drug defendants did not have a duty to warn about another manufacturer's product. *Id.* at *14. While the district court recognized that its rulings left the plaintiff without a legal remedy, it concluded that the issue was one to be addressed by the legislature, not the court. *Id.* at *16–17.

Mensing appealed from the orders dismissing her claims. *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009). On appeal, the Eighth Circuit reinstated her claims against the generic drug defendants only. The appellate court disagreed with the district court's federal preemption analysis. First, the court noted that the Hatch-Waxman amendments did not contain a provision expressly preempting lawsuits against makers of generic drugs. *Id.* at 607. Next, the court concluded that there was no conflict preemption because compliance with both state and federal law was possible. The court rejected the defendants' contention that they could not unilaterally change the label on MCP without prior FDA approval. The court determined that the generic drug defendants "could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved." *Id.* at 608 (emphasis in the original). The court also noted that "[i]n addition to proposing a label change, the generic manufacturers could have suggested that the FDA send out a warning letter to health care professionals." *Id.* at 610. The court further observed that the defendants did not have to market MCP. "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." *Id.* at 611. Finally, the Eighth Circuit held that the obligation the plaintiff sought to impose on the generic drug defendants did not obstruct the purposes or objectives of the Hatch-Waxman amendments, but rather furthered one of the goals of FDA legislation that a manufacturer bears the primary responsibility for its labeling. *Id.* at 612.

Plaintiff Julie Demahy ingested generic MCP from 2002 until 2006. In 2007, she was diagnosed with tardive dyskinesia. She brought suit under Louisiana law against the brand-name drug manufacturer and the generic drug manufacturer, alleging failure to warn of the risks of development of the neurological disorder from long term use of MCP. *Demahy v. Wyeth, Inc.*, 586 F. Supp. 2d 642, 643–44 (E. D. La. 2008). The brand-name defendants were dismissed without prejudice. The generic defendant moved to dismiss the plaintiff's failure to warn claims on grounds of federal conflict preemption. *Id.* at 643. The district court denied the motion. The court examined the federal statutes and regulations and concluded that "the statutory scheme governing the premarketing approval for drugs simply does not evidence Congressional intent to insulate generic drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law." *Id.* at 657. The generic manufacturer appealed to the Fifth Circuit, but the appellate court affirmed the lower court's ruling, denying dismissal on conflict preemption grounds. 593 F.3d 428 (5th Cir. 2010).

Pliva, Inc. v. Mensing—The United State Supreme Court's Opinion

The United States Supreme Court granted certiorari to determine whether federal statutes and FDA regulations preempted state tort law failure to warn claims against generic drug manufacturers. *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567. The plaintiffs argued that the manufacturers knew or should have known that MCP product label did not adequately warn of the risk that long term use of MCP carried the high risk of tardive dyskinesia, and that state law required the use of a different, stronger label. *Id.* at 2574. The defendants argued that federal statutes and regulations required them to use the same labeling as the brand-name drug. Therefore, it was impossible for them to comply with federal law if under state tort law they were required to use a different label. *Id.* at 2573. The United States filed a brief explaining the FDA's interpretation of the federal labeling laws and regulations at issue.

The court in the *In re Darvocet* litigation rejected this "failure to timely communicate" argument because the plaintiffs' pleadings lacked the basic factual allegations necessary to state a claim for relief based on such a theory.

The Court examined the history of labeling changes to the drug. The MCP label had changed over time to address the risk of developing tardive dyskinesia. In 1985, the label was revised to warn that patients who take metoclopramide may develop tardive dyskinesia, and that therapy longer than 12 weeks has not been evaluated. *Id.* at 2572. In 2004, the reference listed drug (RLD) manufacturer sought and was granted a label change that added that therapy should not exceed 12 weeks in duration. *Id.* at 2572–73. In 2009, the FDA ordered that a boxed warning be included, which stated that treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases. *Id.* at 2573.

The Supreme Court noted that the first step in any conflict preemption analysis is a comparison of state and federal law. *Id.* at 2573. The Court focused on the central issue in dispute—"whether, and to what extent, generic manufacturers may change their labels *after* initial FDA approval." *Id.* at 2574. While the plaintiffs contended that the generic manufacturers could have changed their labels using either the FDA's "changes being effected" (CBE) process or Dear Doctor letters, the FDA disagreed. "The agency interprets the CBE regulation to allow changes to generic labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." *Id.* at 2575 (citations omitted). Thus the generic manufacturers could not use the CBE process to change the label on MCP unilaterally. Furthermore, the FDA considers Dear Doctor letters to be labeling, and therefore "such letters must be 'consistent with and not contrary to [the drug's] approved… labeling.'" *Id.* at 2576. Consequently, Dear Doctor letters also could not be used to change the label unilaterally.

The FDA, however, posited another way that the defendants could have changed the MCP label. The FDA maintained that a generic drug manufacturer has a duty to propose a stronger warning if it believes such a warning is warranted. *Id.* The source for this duty, the FDA contended, is found in the preamble to its 1992 regulations, which implemented the Hatch-Waxman amendments. The Supreme Court ultimately concluded that it did not need to address whether such a duty existed in order to decide the case. The Supremacy Clause of the United States Constitution provides that federal law is the supreme law of the land, and to the extent that anything in the constitution or laws of any state is contrary to federal law, state law must give way. State law is contrary to federal law when it is impossible for a person to comply with both. Here, the Court decided it was impossible for the generic manufacturer defendant to comply with both state and federal law. "The federal duty to ask the FDA for help in strengthening the corresponding brand name label, assuming such a duty exists, does not change this analysis. Although requesting FDA assistance would have satisfied the Manufacturers' federal duty, it would not have satisfied their state tort law duty to provide adequate labeling. State law demanded a safer label; it did not instruct the Manufacturers to communicate with

the FDA about the possibility of a safer label." *Id.* at 2578.

The Court rejected the plaintiffs' contention that the defendants could not rely on a conflict preemption defense unless they could prove that the FDA would not have allowed them to comply with state law. The Court found that this approach would "render conflict pre-emption largely meaningless." *Id.* at 2579. The Court explained that "preemption analysis should not involve speculation about ways in which federal agency and third-party actions could potentially reconcile federal duties with conflicting state duties." *Id.* 2580.

The Court realized that in finding that the plaintiffs' claims against the generic drug manufacturers were subject to dismissal based upon federal conflict preemption, the result seemed harsh because had the plaintiffs ingested the brand-name drug, their failure to warn claims against the brand-name manufacturer would not have been preempted. The Court, however, explained:

> It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme. As always, Congress and the FDA retain the authority to change the law and regulations if they so desire.

Id. at 2582. The Supreme Court, therefore, reversed the judgments of both the Fifth and Eighth Circuit and remanded the cases for further proceedings consistent with the Court's opinion.

Plaintiffs' Post-*Mensing* Attempts to Avoid the Federal Conflict Preemption Defense

Since the Supreme Court's decision in *Mensing*, plaintiffs continue to pursue state law product liability claims against generic drug manufacturers. The plaintiffs' difficulty has been in pleading theories of recovery that are not premised upon state law failure to warn doctrines. The following is a summary of arguments asserted by plaintiffs in an effort to avoid the federal conflict preemption defense.

In *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011), the plaintiffs brought suit against the brand-name drug defendants and the generic drug defendants, seeking damages allegedly caused by the plaintiffs' ingestion of generic metoclopramide. The district court granted summary judgment to the brand-name drug defendants because the plaintiffs had not ingested their drug, and to the generic drug defendants on the basis that federal conflict preemption barred their claims. The plaintiffs appealed.

Generally, if the cause of action is premised on failure to warn, then the claim should be subject to dismissal pursuant to the Supreme Court's holding in *Mensing*.

The case was argued in the Sixth Circuit on June 9, 2010, approximately one year prior to the *Mensing* decision. After the *Mensing* decision was issued, the plaintiffs sought and were granted permission to submit supplemental briefing on the preemption issue. On September 22, 2011, the Sixth Circuit affirmed the lower court's judgment as to the generic drug defendants in light of the Supreme Court's holding in *Mensing*. The Sixth Circuit also affirmed the lower court's judgment in favor of the brand-name drug defendants, specifically rejecting the plaintiffs' argument that the brand-name drug defendants could be held liable because "the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs." *Id.* at 423–24. The plaintiffs asserted that Kentucky state courts would adopt this vicarious liability theory under the Kentucky Products Liability Act. The Sixth Circuit disagreed, observing that all but one of the courts considering this argument had rejected it. The Sixth Circuit also was not convinced by the plaintiffs' argument that Kentucky courts would adopt such a theory of liability. *Id.* at 424.

On February 21, 2012, the *Smith* plaintiffs filed a petition for writ of certiorari. In their petition, they took issue with the Sixth Circuit's decision on multiple grounds. They claimed that the Sixth Circuit failed to consider the generic drug defendants' duties under Kentucky law. The plaintiffs maintain that Kentucky law allows a claim for strict liability and negligence based upon the defendant's decision to sell a product containing an inadequate warning. They contend the warning itself is just a factor to be considered in determining whether the product is unreasonably dangerous. The plaintiffs also argued that Kentucky law does not require a defendant to provide a safer or stronger warning. Instead, it requires the manufacturer to review the design of its product and to make an effort to notify customers if it determines that the design is defective. Plaintiffs further assert that under Kentucky law a manufacturer may be held liable if the warnings are not conveyed in a manner likely to reach and be comprehended by the purchaser and user of the product. Despite these arguments, on April 30, 2012, the *Smith* plaintiffs' petition for writ of certiorari was denied by the Supreme Court. *Smith v. Wyeth, Inc.*, No. 11-1046, 2012 U.S. Lexis 3319 (U.S. Apr. 30, 2012).

The plaintiffs in *Smith* also alleged that their other causes of action—breach of express and implied warranties, design defect, unfair trade practices, negligent testing, and negligent post-marketing surveillance—were not failure to warn claims, and therefore should not be subject to *Mensing* preemption. They argued that these "other" causes of action do not impose labeling requirements that conflict with federal law.

Summary of Post-*Mensing* Decisions

[This article does not include a survey of state court opinions addressing the holding in *Mensing*.]

Court	Case Name	Holding	Generic Drug
First Circuit	*Bartlett v. Mutual Pharm. Co., Inc.*, No. 10-2277, 2012 U.S. App. Lexis 9050 (1st Cir. May 2, 2012)	The holding in *Pliva, Inc. v. Mensing* does not preempt state law design defect claims against generic drug manufacturers	sulindac
Fifth Circuit	*Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011)	On remand from the U.S. Supreme Court, the Fifth Circuit vacated the district court's order denying in part the generic drug defendant's motion to dismiss, and remanded the case for entry of judgment in favor of the generic drug defendant	metoclopramide
Sixth Circuit	*Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011), petition for writ of certiorari filed by plaintiff on Feb. 21, 2012; *cert. denied* in *Smith v. Wyeth, Inc.*, No. 11-1046, 2012 U.S. Lexis 3319 (U.S. Apr. 30, 2012)	Generic drug defendants' motion to dismiss granted, brand-name drug defendants motion to dismiss granted	metoclopramide
Eighth Circuit	*Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011)	On remand from the U.S. Supreme Court, the Eighth Circuit vacated sections I, II, and IV of its prior opinion, which had reversed the district court's judgment in favor of the generic drug defendants	metoclopramide
Ninth Circuit	*Gaeta v. Perrigo Pharm. Co.*, No. 09-15001, 2012 U.S. App. Lexis 3907 (9th Cir. Feb. 27, 2012); *see* the Ninth Circuit's prior decision at 630 F.3d 1225, (9th Cir. 2011), *vacated by L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497; 181 L. Ed. 2d 343; 2011 U.S. LEXIS 7720 (U.S. Oct. 31, 2011)	Generic drug defendant's motion for summary judgment affirmed by the Ninth Circuit following the U.S. Supreme Court's order vacating the Ninth Circuit's prior decision reversing the district court's grant of summary judgment.	Ibuprofen
S.D. Alabama	*Brasley-Thrash v. Teva Pharm. USA, Inc.*, No. 10-00031, 2011 U.S. Dist. Lexis 102858 (S.D. Ala. Sept. 12, 2011)	Plaintiff's motion for leave to amend complaint to dismiss claims preempted by *Mensing*, and to add claims plaintiff asserts are not preempted by *Mensing*, granted	metoclopramide
S.D. Alabama	*Scott v. Baxter Healthcare Corp.*, No. 10-0186, 2011 U.S. Dist. Lexis 101598 (S.D. Ala. Sept. 9, 2011)	Generic drug defendant's motion for summary judgment granted	promethazine hydrochloride
E.D. Arkansas	*Bell v. Pliva, Inc.*, No. 5:10-cv-00101, 2012 U.S. Dist. Lexis 19859 (E.D. Ark., Feb. 16. 2012)	Generic drug defendant's motion to dismiss granted	metoclopramide
E.D. Arkansas	*Fullington v. Pliva, Inc.*, No. 4:10-cv-00236, 2012 U.S. Dist. Lexis 142931 (E.D. Ar. Dec. 12, 2012)	Generic drug defendants' motion to dismiss granted	metoclopramide
E.D. Arkansas	*Fullington v. Pliva, Inc.*, No. 4:10-cv-00236, 2012 U.S. Dist. Lexis 71589 (E.D. Ark. May 23, 2012)	Generic drug defendants' motion to dismiss amended complaint asserting claim for alleged failure to update warnings granted where plaintiff alleged even the revised warnings were inadequate until February of 2009, and there was no evidence plaintiff took the generic drug after that date. Plaintiffs were given fourteen days to offer evidence of ingestion post February of 2009 in order to avoid dismissal	metoclopramide
M.D. Florida	*In re Accutane Products Liability*, MDL 1626, No. 8:4-MD-2523-T-30, NO. 8:10-cv-987, 2011 U.S. Dist. Lexis 150106 (M.D. Fla. Nov. 9, 2011)	Generic drug defendants' motion for judgment on the pleadings granted	isotretinoin
M.D. Florida	*Guarino v. Wyeth LLC*, NO. 8:10-cv-2885, 2011 U.S. Dist. Lexis 128630 (Nov. 7, 2011), plaintiff's motion for reconsideration of the court's Nov. 7, 2011 order denied at 2012 U.S. Dist. 1188 (M.D. Fla. Jan. 5, 2012)	Generic drug defendant's motion to dismiss or alternatively, motion for judgment on the pleadings granted	metoclopramide

Court	Case Name	Holding	Generic Drug
M.D. Florida	*Metz v. Wyeth, Inc.*, No. 8:10-cv-2658, 2012 U.S. Dist. Lexis 42432 (M.D. Fla. Mar. 28, 2012)	Generic drug defendant's motion to dismiss granted in part, denied in part, motion for summary judgment granted	metoclopramide
S.D. Georgia	*Coney v. Mylan Pharm., Inc.*, No. 6:11-cv-35, 2012 U.S. Dist. Lexis 6284 (S.D. Ga. Jan. 19, 2012)	Generic drug defendant's motion for summary judgment granted	phenytoin sodium
N.D. Georgia	*Henderson v. Sun. Pharm. Industries, Ltd.*, 809 F. Supp. 2d 1373 (N. D. Ga. 2011)	Plaintiff's motion to amend denied, generic drug defendant's motion to dismiss granted	phenytoin sodium and fosphenytoin
N.D. Georgia	*Moore v. Mylan, Inc.*, No. 1:11-cv-03037, 2012 U.S. Dist. Lexis 6897 (N.D. Ga. Jan. 5, 2012)	Generic drug defendant's motion to dismiss granted	phenytoin
S.D. Indiana	*Schork v. Baxter Healthcare Corp.*, No. 4:10-00005, 2011 U.S. Dist. Lexis 107687 (S. D. Ind. Sept. 22, 2011)	Generic drug defendant's motion for summary judgment granted	promethazine HCL
E.D. Kentucky	*In re Darvocet, Darvon and Propoxyphene Products Liability Litigation*, MDL 2226, 2012 U.S. Dist. Lexis 30593 (E.D. Ky. Mar. 5, 2012)	Generic drug defendants' motion to dismiss granted	propoxyphene
M.D. Louisiana	*Cooper v. Wyeth, Inc.*, No. 09-929, 2012 U.S. Dist. Lexis 29209 (M.D. La. Mar. 6, 2012)	Generic drug defendants' motion to dismiss granted in part, denied in part	metoclopramide
E.D. Louisiana	*Beck v. Teva Pharm. Industries Ltd.*, No. 10-901, 2011 U.S. Dist. Lexis (E.D. La. Sept. 12, 2011)	Generic drug defendants' motion to dismiss granted	metoclopramide
E.D. Louisiana	*Boyer v. Wyeth, Inc.*, No. 09-6123, 2012 U.S. Dist. Lexis 19150 (E.D. La. Jan. 11, 2012)	Generic drug defendants' motion for judgment on the pleadings granted	metoclopramide
E.D. Louisiana	*Brown v. Actavis Elizabeth, LLC*, No. 10-11, 2011 U.S. Dist. Lexis 89393 (E.D. La. Aug. 10, 2011)	Generic drug defendant's motion to dismiss granted	metoclopramide
E.D. Louisiana	*Pellegrin v. Qualitest Pharm., Inc.*, No. 10-2121, 2012 U.S. Dist. Lexis 19152 (E.D. La. Jan. 10, 2012)	Generic drug defendants' motions for judgment on the pleadings granted	metoclopramide
E.D. Louisiana	*Waguespack v. Pliva USA, Inc.*, No. 10-692, 2011 U.S. Dist. Lexis 135710 (E.D. La. Nov. 3, 2011)	Generic drug defendants' motions for judgment on the pleadings granted	metoclopramide
E.D. Louisiana	*Whitener v. Pliva, Inc.*, No. 10-1552, 2011 U.S. Dist. Lexis 140053 (E.D. La. Dec. 6, 2011)	Generic drug defendants' motions for judgment on the pleadings granted in part, denied in part	metoclopramide
E.D. Louisiana	*Whitener v. Pliva Inc.*, No. 10-1552, 2012 U.S. Dist. Lexis 76822 (E.D. La. June 4, 2012)	Generic drug defendants' joint motion to dismiss amended complaint asserting a claim for off-label marketing in violation of federal law denied	metoclopramide
W.D. Louisiana	*Barfield v. Wyeth, Inc.*, No. 09-2012, 2102 U.S. Dist. Lexis 19384 (W.D. La. Jan. 4, 2012)	Generic drug defendant's motion to dismiss granted	metoclopramide
W.D. Louisiana	*Guilbeau v. Wyeth Inc.*, No. 09-1652, 2011 U.S. Dist. Lexis 119251 (W.D. La. Oct. 14, 2011)	Generic drug defendant's motion for judgment on the pleadings granted	metoclopramide
W.D. Louisiana	*Johnson v. Teva Pharm. USA, Inc.*, No. 2:10cv404, 2012 U.S. Dist. Lexis 71384 (W.D. La. May 21, 2012).	Generic drug defendants' motion for judgment on the pleadings granted	metoclopramide
W.D. Louisiana	*Stevens v. Pliva, Inc.*, No. 6:10-0886, 2011 U.S. Dist. Lexis 147684 (W.D. La. Nov. 14, 2011)	Magistrate judge recommendation that generic drug defendant's motion to dismiss be granted	metoclopramide
W.D. Louisiana	*Richardson v. Wyeth, Inc.*, No. 10-0883, 2011 U.S. Dist. Lexis 128529 (W.D. La. Nov. 6, 2011)	Generic drug defendant's motion to dismiss granted	metoclopramide
D. Maryland	*Grinage v. Mylan Pharm., Inc.*, No. CCB-11-1436, 2011 U.S. Dist. Lexis 149667 (D. Md. Dec. 30, 2011)	Generic drug defendant's motion to dismiss granted	allopurinol

Summary of Post-*Mensing* Decisions, *continued*

Court	Case Name	Holding	Generic Drug
D. Maryland	*Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654 (D. Md. 2011), plaintiff's motion to alter or amend the court's Nov. 22, 2011 order denied at 2012 U.S. Dist. Lexis 11154 (D. Md. Jan. 27, 2012)	Generic drug defendant's motion for judgment on the pleadings granted	metoclopramide
D. Minnesota	*Bowman v. Wyeth, LLC*, No. 10-1946, 2012 U.S. Dist. Lexis 27795 (D. Minn. Mar. 2, 2012)	Generic drug defendant's motion for judgment on the pleadings granted	metoclopramide
W.D. Missouri	*Brinkley v. Pfizer, Inc.*, No. 10-0274, 2012 U.S. Dist. Lexis 62569 (W.D. Mo. Apr. 12, 2012)	Generic drug defendant's motion for judgment on the pleadings granted	metoclopramide
D. Nevada	*Moretti v. Pliva, Inc.*, No. 2:08-cv-00396, 2012 U.S. Dist. Lexis 24113 (D. Nev. Feb. 27, 2012)	Generic drug defendant's motion to dismiss granted	metoclopramide
D. New Jersey	*In re Fosamax (Alendronate Sodium) Products Liability Litigation*, MDL 2243, No. 3:08-cv-00008, 2012 U.S. Dist. Lexis 5817 (D. N.J. Jan. 17, 2012)	Generic drug defendants' motion for judgment on the pleadings granted	alendronate sodium
D. New Jersey	*Welsh v. Merck Sharpe & Dohme Corp.*, No. 11-3045, 2012 U.S. Dist. Lexis (D. N.J. Apr. 2, 2012)	In deciding a motion to remand, the court severed the claims of all the plaintiffs in this multi-plaintiff action, and dismissed the diverse plaintiffs' claims against the generic drug defendants	alendronate sodium
Superior Court of New Jersey	*In re Reglan Litigation*, Case No. 289, Superior Court of New Jersey, (Atlantic and Cape May Counties) May 4, 2012	Generic drug defendants' motion to dismiss granted except as to any claims against a generic manufacturers that did not change the label to match the label of the brand name drug	metoclopramide
Superior Court of New Jersey	*In re Reglan Litigation*, Case No. 289, Superior Court of New Jersey, (Atlantic and Cape May Counties) May 4, 2012	Generic drug defendants' motion to dismiss granted even though the FDA had designated the drug as the RLD	metoclopramide
E.D. New York	*Bartoli v. APP Pharm., Inc.*, No. 09-MD-2120, 2012 U.S. Dist. Lexis 10901 (E.D. N.Y. Jan. 30 2012)	Generic drug defendants' motion to dismiss granted	pamidronate
W.D. North Carolina	*Couick v. Wyeth, Inc.*, No. 3:09-cv-210, 2012 U.S. Dist. Lexis 3699 (W.D. N.C. Jan. 11, 2012)	Generic drug defendants' motion to dismiss granted in part, denied in part	metoclopramide
N.D. Ohio	*Fulgenzi v. Pliva, Inc.*, No. 5:09-cv-1767, 2012 U.S. Dist. Lexis 45620 (N.D. Ohio Mar. 31, 2012)	Generic drug defendant's motion to dismiss granted	metoclopramide
D. Oregon	*Phelps v. Wyeth, Inc.*, No. 09-cv-6168, 2012 U.S. Dist. Lexis 57967 (D. Or. Apr. 24, 2012)	Generic drug defendant's motion to dismiss granted in all respects, except as to plaintiffs' negligence per se claim based upon an alleged failure to update the label	metoclopramide
D. South Carolina	*Fisher v. Pelstring*, No. 4:09-cv-00252, 2012 U.S. Dist. Lexis 18729 (D. So. Ca. Jan. 11, 2012)	Generic drug defendant's motion to dismiss denied, motion for reconsideration granted in part, denied in part	metoclopramide
S.D. Texas	*Del Valle v. Pliva, Inc.*, No. B:11-13, 2011 U.S. Dist. Lexis 153473 (S. D. Tex. Dec. 21, 2011)	Magistrate judge recommendation that generic drug defendants' motion to dismiss be granted	metoclopramide
S.D. Texas	*Eckhardt v. Qualitest Pharm. Inc.*, No. M-11-235, 2012 U.S. Dist. Lexis 62202 (S.D. Tex. Apr. 30, 2012)	Generic drug defendants' motion to dismiss granted	metoclopramide
D. Vermont	*Kellogg v. Wyeth*, No. 2:07-cv-82, 2012 U.S. Dist. Lexis 13182 (D. Vt. Feb. 3, 2012)	Generic drug defendants' motion for judgment on the pleadings granted, plaintiff's motion to amend denied	metoclopramide
D. Vermont	*Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 U.S. Dist. Lexis 13185 (D. Vt. Feb. 3, 2012)	Generic drug defendants' motion for judgment on the pleadings granted in part, denied in part	metoclopramide

"Other" causes of action similar to those asserted in *Smith* recently were considered and dismissed on *Mensing* preemption grounds by the district court in the *In re Darvocet, Darvon and Propoxyphene Products Liability Litigation*, MDL 2226, 2012 U.S. Dist. Lexis 30593 (E.D. Ky. Mar. 5, 2012).

In the *In re Darvocet* litigation, the plaintiffs sued both the brand-name drug defendants and the generic drug defendants for injuries allegedly caused by prescription pain medication sold under the brand names Darvon and Darvocet, and under the generic name propoxyphene. The court granted the generic drug defendants' motions to dismiss based on federal conflict preemption after giving the plaintiffs the opportunity to amend their complaints following the Supreme Court's decision in *Mensing*.

In the amended complaints, the plaintiffs asserted claims for design defect (strict liability), defect due to inadequate warning (strict liability), negligent design, negligence, negligent failure to warn, fraudulent nondisclosure, negligent misrepresentation, statutory negligence, breach of express warranty, and breach of implied warranty. *Id.* at *100–01. In an effort to distinguish their claims from failure to warn claims, the plaintiffs asserted that "they '[we]re not contending that the Generic Defendants should have added new, unapproved warnings about propoxyphene's risks,' but rather 'that the Generic Defendants knew their product was unreasonably dangerous and should have voluntarily withdrawn it form the market.'" *Id.* at *101. Thus their central claim was that the defendants "wrongfully marketed an unreasonably dangerous product." *Id.*

The plaintiffs included within their wrongful marketing claim their causes of action for design defect, negligent design, negligence, and breach of implied warranty. *Id.* at *102. The plaintiffs attempted to rely on two Sixth Circuit cases finding no preemption of state tort law claims. However, both cases were decided before *Mensing*, and involved the alleged wrongdoing of a brand name drug manufacturer in the process leading up to FDA approval of a drug. The court distinguished those cases from the instant case, which involved the conflict between state and federal law arising out of the sameness requirement imposed by the FDA on generic drug defendants. *Id.* at *103–04. The court then turned to the plaintiffs' contention that the generic drug defendants simply could have removed their product from the market if their warnings were inadequate. The court observed that this argument already had been rejected by the Supreme Court in the Respondents' Petition for Rehearing in *Pliva Inc. v. Mensing*, [*id.* at *105, citing 131 S. Ct. 2567, 180 L. Ed. 2d 580 (July 18, 2011) (No. 09-993), 2011 U.S. S. Ct. Briefs Lexis 878 at*3–6], by the Eighth Circuit on remand in the *Mensing* case, and by the Sixth Circuit in the *Smith* case. Consequently, it was not a basis for arguing that there was no conflict between state and federal law, and allowing such an argument would render conflict preemption largely meaningless. *In re Darvocet* at *107.

There is no doubt that the argument for expanding *Mensing*'s holding to state law design defect claims will be the subject of additional argument in the courts for many months to come.

The court next considered plaintiffs' argument that the generic drug defendants could be sued on warning claims based on the manufacturers' alleged failure to update or communicate subsequent approved revisions to the brand name drug's warnings in a timely manner. Post-*Mensing*, a handful of courts in the metoclopramide litigation have declined to dismiss state law tort claims against generic drug defendants that are based on an alleged failure to either incorporate or communicate FDA-approved revisions to the warnings for the brand name drug. For instance, in *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 U.S. Dist. Lexis 13185 (D. Vt. Feb. 3. 2012), the court granted in part and denied in part the generic drug defendants' motion for judgment on the pleadings. The motion was denied in relation to the assertion of a state tort claim based upon the defendants' alleged failure to revise the generic metoclopramide label to include labeling changes approved for the branded drug. The court reasoned that once the branded drug's label had been changed, the generic drug defendant was free to change its label as well and, therefore, it would not have been impossible for the generic drug defendant to comply with federal law. *See also Fisher v. Pelstring*, No. 4:09-cv-00252, 2012 U.S. Dist. Lexis 18729 (D. So. Ca. Jan. 11, 2012); *Cooper v. Wyeth, Inc.*, No. 09-929, 2012 U.S. Dist. Lexis 29209 (M.D. La. Mar. 6, 2012); *Couick v. Wyeth, Inc.*, No. 3:09-cv-210, 2012 U.S. Dist. Lexis 3699 (W.D. N.C. Jan. 11, 2012); *Brasley-Thrash v. Teva Pharm. USA, Inc.*, No. 10-00031, 2011 U.S. Dist. Lexis 102858 (S.D. Ala. Sept. 12, 2011); *In re Reglan Litigation*, Case No. 289, Superior Court of New Jersey, May 4, 2012 (these courts ruled that the plaintiffs could assert certain state law tort claims based on the generic drug defendants' alleged failure to either incorporate a FDA-approved revision to a warning for the brand-name drug into the generic drug's labeling, or to otherwise communicate the FDA-approved revision such as in the form of a consistently worded Dear Doctor letter). The court in the *In re Darvocet* litigation rejected this "failure to timely communicate" argument because the plaintiffs' pleadings lacked the basic factual allegations necessary to state a claim for relief based on such a theory. *Id.* at *109.

The court also rejected another failure to warn theory premised upon the assertion that a generic drug defendant can be treated like a brand name drug defendant for preemption purposes in certain circumstances. The plaintiffs asserted that these circumstances occur when a brand name drug is withdrawn from the market and there no longer is a holder of a NDA for the drug. In such circumstances, the FDA will unilaterally designate one of the generics still on the market as the reference listed drug or "RLD." This is done

so that there will be a drug to serve as the source for establishing bioequivalence for any other generics of the same drug. The plaintiffs argued that an RLD designation by the FDA means that the particular generic drug defendant whose product has been designated as the RLD cannot assert preemption under *Mensing*. This argument was soundly rejected by the court based upon multiple FDA publications indicating that in such circumstances the FDA, not the RLD holder, controls the labeling changes for the drug. *Id.* at *112–113. *See also*, *In re Reglan Litigation*, Case No. 289, Superior Court of New Jersey, May 4, 2012 (the court granted two generic defendants' motion to dismiss. holding that the unilateral designation by the FDA of a specific generic drug as a RLD does not turn the generic drug ANDA holder into a NDA holder (*i.e.*, a brand name drug defendant) for purposes of *Mensing*).

The court then looked at the plaintiffs' causes of action for misrepresentation, fraud, violation of consumer protection statutes, breach of express warranty, and statutory negligence, and concluded that all were premised upon a failure to warn. The plaintiffs admitted that their misrepresentation, fraud, and violation of consumer protection statutes claims all challenged the content of the drug's label. Furthermore, any breach of express warranty necessarily was based on the label's content. Therefore, all these claims were found to be preempted pursuant to *Mensing*.

That left only the statutory negligence claim. Pursuant to the complaint, this cause of action was based upon the defendants' alleged violation of federal standards for the sale of prescription drugs, and mostly based upon violation of FDA regulations relating to labeling or misbranding. *Id.* at *114. The court concluded that based on *Mensing*, the plaintiffs could not bring this claim to the extent that it was premised upon a challenge to the content of the labels. The court also concluded that the plaintiffs could not bring this claim if it was premised upon an alleged failure to comply with the Food Drug and Cosmetic Act because such claims are preempted by Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), cited by the Supreme Court in *Mensing*. Plaintiffs have no private right of action to enforce the FDCA. *In re Darvocet* at *114–15.

The court also rejected the plaintiffs' contention that they should be allowed to take discovery and have another chance to amend their complaint. First, the plaintiffs acknowledged during oral argument that if the court found their claims to be preempted there would be no reason to amend. Second, under *Iqbal*, a plaintiff is not entitled to take discovery to fix a factually deficient complaint. *Id.* at *116.

> Despite the many defense wins for generic drug manufacturers since the *Mensing* opinion was issued last year, consumer groups have not been idle in attempting to challenge the decision.

The *In re Darvocet* decision demonstrates that regardless of the title of the cause of action, the key is an examination of the factual allegations supporting the cause of action. Generally, if the cause of action is premised on failure to warn, then the claim should be subject to dismissal pursuant to the Supreme Court's holding in *Mensing*. The table on pages 18–20 contains a summary of the numerous opinions that have been issued since *Mensing*, and illustrates that most of the cases have resulted in dismissal of the claims asserted against the generic drug defendants.

Plaintiffs have advanced yet another theory of liability in the recently decided case *Whitener v. Pliva, Inc.*, No. 10-1552, 2012 U.S. Dist. Lexis 76822 (E.D. La. June 4, 2012). In *Whitener* the plaintiffs were permitted to file an amended complaint following the dismissal of their claims against the generic drug defendants contained in the initial complaint. In the amended complaint the plaintiffs attempted to assert a non-preempted state-law claim based on the generic drug defendants' alleged promotion of their drug for off-label purposes in violation of federal law. The defendants challenged the amended complaint on *Mensing* preemption grounds. The court concluded that the fact that a generic drug ultimately is prescribed off-label does not avoid *Mensing* preemption. *Id.* at *11–12. The court noted, however, that "[t]he harder question, and the one that Plaintiffs do not clearly address, is whether the *Mensing* analysis changes if a generic defendant *actively promotes* the drug for off-label use in violation of federal law, and to that extent *Mensing* would seem to control." *Id.* at 12 (emphasis in original). The court explained "[i]f a generic pharmaceutical manufacturer has failed to comply with federal requirements from the outset by marketing a drug off-label, it may be appropriate for liability to be imposed for failing to warn of risks associated with the off-label purpose which the manufacturer should not have been promoting in the first place." *Id.* 12–13. Since the parties could not cite to any post-*Mensing* case addressing off-label promotion, the court was reluctant to dismiss the plaintiffs' claim, but did not rule out the possibility of revisiting the issue at a later time. *Id.* at 13.

The First Circuit also recently considered a post-*Mensing* preemption argument in a different context—one involving a state law design defect claim. In *Bartlett v. Mutual Pharm. Co., Inc.*, No. 10-2277, 2012 U.S. App. Lexis 9050 (1st Cir. May, 2, 2012), the plaintiff alleged that the defendant's generic non-steroidal anti-inflammatory drug was designed defectively because its risks outweighed its benefits, making it unreasonably dangerous to consumers. At a 2009 trial, two years before the Supreme Court's decision in *Mensing*, the jury returned a verdict for the plaintiff. The generic drug manufacturer appealed. On appeal, the defendant argued that because generic drug manufacturers cannot alter the composition of a generic drug, the Supreme Court's reasoning in *Mensing*,

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supporting federal preemption of state law failure to warn claims, should apply with equal force to preemption of state law design defect claims against generic drug manufacturers. The First Circuit rejected this *Mensing* argument in the context of a state law design defect claim. Relying on the Supreme Court's holding in *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), the First Circuit concluded that even if the generic drug manufacturer could not have changed the composition of the drug, it could have decided not to sell the drug. *Bartlett*, 2012 U.S. App. Lexis 9050 at *12–13. As explained by the court, "[o]n balance, we conclude that the Court adopted a general no-preemption rule in *Wyeth* and that it is up to the Supreme Court to decide whether *Pliva*'s exception is to be enlarged to include design defect claims." *Id.* at *14. There is no doubt that the argument for expanding *Mensing*'s holding to state law design defect claims will be the subject of additional argument in the courts for many months to come. Just three weeks after the *Bartlett* decision, in *Fullington v. Pliva, Inc.*, No. 4:10cv00236, 2012 U.S. Dist. Lexis 71589 (E.D. Ark. May 23, 2012) the plaintiffs attempted to advance a design defect claim against a generic drug defendant in reliance on *Bartlett*. The court distinguished the claim, however, because in *Bartlett* the liability theory was that the drug was unreasonably dangerous because its risks allegedly outweighed its benefits. In *Fullington*, on the other hand, the liability theory was that the drug was unreasonably dangerous when taken longer than the recommended duration of use. This was seen as a concession that the drug was not unreasonably dangerous when used properly, and, therefore, the plaintiffs' design defect claim was really a failure to warn claim subject to *Mensing* preemption.

A Legislative Proposal to Undo *Pliva, Inc. v. Mensing*

Despite the many defense wins for generic drug manufacturers since the *Mensing* opinion was issued last year, consumer groups have not been idle in attempting to challenge the decision. On April 18, 2012, Senator Patrick Leahy, chairman of the Senate Judiciary Committee, introduced Senate Bill 2295, seeking a legislative reversal of the Supreme Court's holding in *Pliva v. Mensing*. April 18, 2012, Congressional Record—Senate, at p. S2497. The bill has been co-sponsored by Senators Jeff Bingaman, Richard Blumenthal, Sherrod Brown, Chris Coons, Al Franken, Sheldon Whitehouse, and Mark Begich. Over forty state attorneys general also have expressed their support for the bill via letter dated May 11, 2012 to Senators Leahy and Franken. The letter is available on the website of the National Association of Attorneys General at: http://www.naag.org/ (last visited by the author on June 7, 2012).

The bill, titled the Patient Safety and Generic Labeling Improvement Act, is described as "[a] bill to permit manufacturers of generic drugs to provide additional warnings with respect to such drugs in the same manner that the Food and Drug Administration allows brand names to do so." April 18, 2012, Congressional Record—Senate, at p. S2497. The bill has the support of the AARP, Public Citizen, and the Alliance for Justice, among other consumer groups. *Id.* at p. S2498. The text of the bill as proposed on April 18, 2012, provides:

> Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
>
> SECTION 1. SHORT TITLE.
>
> This Act may be cited as the ``Patient Safety and Generic Labeling Improvement Act''.
>
> SEC. 2. WARNING LABELING WITH RESPECT TO GENERIC DRUGS.
>
> Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended by adding at the end the following:
>
> (11)(A) Notwithstanding any other provision of this Act, the holder of an approved application under this subsection may change the labeling of a drug so approved in the same manner authorized by regulation for the holder of an approved new drug application under subsection (b).
>
> (B) In the event of a labeling change made under subparagraph (A), the Secretary may order conforming changes to the labeling of the equivalent listed drug and each drug approved under this subsection that corresponds to such listed drug.

Id. It is too early in the legislative process to determine whether this bill will become law. For additional information regarding the bill, visit the Library of Congress' website at: http://thomas.loc.gov/home/bills_res.html (last visited by the author on May 30, 2012).

Conclusion

The holding in *Mensing* is under attack both in Congress and in the courts. It is too early to tell if Congress will pass legislation nullifying *Mensing*. In the meantime, generic drug manufacturers should stand their ground against the plaintiffs' state law failure to warn claims disguised as some other cause of action. By focusing on the factual allegations underpinning such claims, generic drug manufacturers can demonstrate that such claims are merely an effort to bypass *Mensing*. For now, generic drug manufacturers appear to have momentum in the battle to defeat state law failure to warn claims on federal conflict preemption grounds. It will be interesting to watch in the coming months whether *Mensing*'s holding will be expanded to include state law design defect claims against generic drug manufacturers.