

## Generic vs. Branded Liability: *Mensing* Holds Sway Until FDA Completes Rulemaking

***FDA's delay on the final version of generic labelling rules until April 2017 means both branded and generic drug manufacturers face continued uncertainty.***

The U.S. Food and Drug Administration (FDA) recently announced it will not finalize a rule to allow generic drug manufacturers to independently update their warning labels this summer as planned. The rule would have negated *Pliva v. Mensing*, 131 S.Ct. 2567, 2571 (2011), a 2011 United States Supreme Court case that struck a blow to the plaintiffs' bar by dramatically limiting products liability lawsuits for consumers who took generic versions of prescription drugs. Specifically, as a result of the decision, plaintiffs cannot sue for injuries caused by a generic manufacturer's failure to adequately warn of the drug's side effects and risks — by far the most common theory for products liability claims brought against pharmaceutical companies. In the aftermath of *Mensing*, the FDA proposed rule changes for generic manufacturers while plaintiffs' lawyers searched — with varied success — for ways around the decision's prohibitions. With the FDA's recent announcement, though, experts question the proposed rule's future, resulting in a renewed focus on generic drug manufacturer liability and increased incentive on the plaintiffs' side to continue creative lawyering and lobbying efforts to change the relevant laws. This changing landscape will generate consequences not just for generic manufacturers, but also for branded drug makers. The entire industry therefore has reason to stay on top of the latest trends and past developments.

### ***Pliva v. Mensing: The Inception***

In *Pliva v. Mensing*, the Supreme Court held that federal law preempts any claim brought under state law alleging that a generic drug was accompanied by inadequate warnings.<sup>1</sup> Under federal law, generic drug makers are required to provide labeling and warnings identical to the generic drug's branded counterpart. Claims by injured consumers are brought under state law (whether state statute or common law). Accordingly, if a jury finds that a generic drug's warnings were insufficient and the manufacturer is therefore liable for the plaintiff's injuries, that decision is tantamount to a finding that state law prohibits what federal law already dictated. The Supreme Court agreed with the defendants that in such a scenario, it would be "impossible for the [m]anufacturer to comply with both their state law duty to change the label and their federal law duty to keep the label the same."<sup>2</sup>

Accordingly, the state law claims were preempted by federal law, and the Court's ruling effectively shielded generic drug manufacturers from state failure-to-warn claims. The ruling did not affect similar lawsuits against branded drug manufacturers, because they have the ability under federal law to change their warning labels if necessary, and thus do not face the same impossibility as the generic manufacturers.<sup>3</sup>

Not surprisingly, the *Mensing* decision brought widespread condemnation from the plaintiffs' bar and consumer protection groups. In particular, those groups pointed to what they saw as the inequity that consumers' ability to recover for injuries caused by prescription drugs depended on whether the consumer had taken the branded or generic version. Efforts to legislatively "undo" *Mensing* commenced almost immediately. A bill (The Patient Safety and Generic Labelling Improvement Act) was introduced in the Senate but never progressed past the committee stage. With no action forthcoming from Congress, the FDA proposed a new generic drug labeling rule that would allow generic manufacturers to unilaterally update safety warnings, as branded manufacturers can already do. With such a rule in place, the rationale of the *Mensing* decision would be undercut and generic consumers would once again be able to bring failure-to-warn claims. The FDA was set to announce a final version of the rule in July 2016, but recently delayed that announcement until at least April 2017.

Because the rulemaking process is necessarily a slow one, the plaintiffs' bar did not sit quietly by but instead pursued other theories of liability for their clients. The two main trends in pharmaceutical products liability cases since *Mensing* are discussed below.

### **Failure-to-Update Warnings; A Way Around *Mensing***

In the wake of *Mensing*, federal and state courts began dismissing most product liability claims against generic drug companies. Courts typically recognized that, no matter what clever wording plaintiffs used to characterize their claims as something other than a failure to warn, the gist of those actions were all rooted in the failure-to-warn theory and therefore not actionable.<sup>4</sup> But consumers have had some success against generic manufacturers on a genuinely different theory: that a generic manufacturer failed to update its labeling in a timely manner after new federally approved warnings are added to the brand-name drug's label.

Several federal courts have held that *Mensing* does not prohibit these failure-to-update claims. In one case, a consumer asserted that the FDA had approved strengthened warnings for the branded drug but the generic manufacturer failed to incorporate those new warnings into its labeling and that had it done so, the prescribing physician would have acted differently.<sup>5</sup> The court held *Mensing* did not bar this type of labeling discrepancy because in those circumstances, the generic manufacturer could – and indeed, is required by federal law – to change its labeling too. Similarly, federal district courts in Louisiana,<sup>6</sup> Vermont,<sup>7</sup> and North Carolina<sup>8</sup> have reached the same conclusion, acknowledging that *Mensing* does not preclude these types of claims.

This *Mensing* workaround is limited in application though, only arising when a brand-name warning label is updated and a generic manufacturer mistakenly fails to follow suit. Searching for a theory with broader application, consumers have also looked to hold brand-name manufacturers directly responsible for injuries caused by generic drugs, through a theory called "innovator liability."

### **Bypassing the Generic Manufacturer for the Innovator**

Typically, products liability law requires a direct connection between the manufacturer and the injured consumer. However, because of the unusual dynamic between brand-name and generic drug manufacturers, some courts have departed from this standard by recognizing innovator liability. Innovator liability holds brand-name manufacturers responsible for injuries caused by a generic drug's warnings on classic tort principle of foreseeability of harm: branded manufacturers know that generic versions will have identical warnings and know that many consumers will ultimately use the generic version, thus it is foreseeable to the branded manufacturers that consumers of generic products will be injured by any failure to warn on its part.

Even before *Mensing*, a California court had found branded drug manufacturers could be liable to a generic drug user.<sup>9</sup> The court held because generic and brand-name drugs were required to be identical, a physician's reliance on the brand-name drug's warning in prescribing a generic drug was foreseeable.<sup>10</sup> Further, the court held that a pharmacist's substituting a generic for the brand-name drug as permitted or even required by state law or insurance was also foreseeable. For these reasons, the court concluded a brand-name drug manufacturer may be responsible for injuries caused by a generic drug.<sup>11</sup>

Since *Mensing*, more consumers have pushed for innovator liability in other jurisdictions, but with only limited success. For instance, after plaintiffs succeeded on the theory before Alabama's highest court, the Alabama legislature changed that state's law to prevent such claims. But just last month, a California appellate court affirmed that innovator liability remains the law in California and consumers can hold brand-name drug manufacturers responsible for injuries caused by generic drugs.

## **Conclusion**

*Mensing* foreclosed state failure-to-warn cases against generic drug manufacturers. Since that decision, both the federal government and consumers have attempted to negate its effect. While generic drug manufacturers have been largely (though not entirely) successful in resisting efforts by the plaintiffs' bar to evade *Mensing's* dictates, the landscape remains in flux. The FDA's proposed rule was widely anticipated as likely to force a return to the pre-*Mensing* state of affairs, with branded and generic drug manufacturers equally at risk for failure-to-warn claims. The FDA rule, if ultimately promulgated, would almost certainly breathe new life into failure-to-warn claims against generic manufacturers. But with the rule's future in doubt, the plaintiffs' side will — in the interim — continue to explore new avenues to circumvent *Mensing's* effect. Both the industry and the plaintiffs' bar must closely watch these developments.

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**Endnotes**

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<sup>1</sup> 131 S.Ct. at 2570.

<sup>2</sup> *Id.* at 2570-71.

<sup>3</sup> See *Wyeth v. Levine*, 555 U.S. 555 (2009).

<sup>4</sup> See e.g. *In re Darvocet*, 2012 WL 718618, at \*3-5 (E.D. Ky. Mar. 5, 2012) (dismissing misrepresentation, fraud, consumer protection, express warranty, and statutory negligence claims because all claims relate to the sufficiency of the warning and are therefore preempted); *In re Pamidronate*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012) (dismissing design defect, negligence, breach of express warranty and breach of implied warranty all based on *Mensing*).

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<sup>5</sup> *Fisher v. Pelstring M.D.*, 817 F. Supp. 2d 791, 804-05 (D.S.C. 2011).

<sup>6</sup> *Cooper v. Wyeth, Inc.*, 2012 WL 733846, at \*3-4 (M.D. La. Mar. 6, 2012) (holding the failure of a generic manufacturer to include a federally approved label in subsequent years after production states a claim for relief).

<sup>7</sup> *Lyman v. Pfizer, Inc.*, 2012 WL 368675, at \*5-6 (D. Vt. Feb. 3, 2012) (noting that *Mensing* did not prevent plaintiff from pursuing liability against a generic manufacturer for out of date labeling).

<sup>8</sup> *Couick v. Wyeth Inc.*, 2012 WL 79670, at \*4-5 (W.D.N.C. Jan. 11, 2012) (dismissing defendant's motion to dismiss, holding if defendant's generic drug did not match its brand, a state law claim for failure to include such warnings is not preempted).

<sup>9</sup> *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d. 299 (2008).

<sup>10</sup> *Id.* at 104.

<sup>11</sup> *See id.* at 114.