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The U.S. Supreme Court's June 2011 decision in *Pliva v. Mensing*<sup>2</sup> represents a significant victory for generic pharmaceutical manufacturers. In a 5-4 opinion, authored by Justice Clarence Thomas, the U.S. Supreme Court held that state law actions against generic drug manufacturers for inadequate warnings are in conflict with federal law. Thus, if a warning on a drug label has been approved by the U.S. Food and Drug Administration ("FDA"), then any state law failure to warn claims involving that label is barred or preempted by federal law. As a result of *Mensing*, hundreds of state law failure to warn claims around the country may now need to be dismissed.

#### A. The U.S. Supreme Court's Holding In *Mensing*

The basic contours of *Mensing* are familiar by now. The plaintiffs in *Mensing* were a series of individuals who took a generic version of the digestive drug metaclopramide -- a drug originally marketed by Wyeth under the brand name Reglan. These individuals subsequently developed a muscular disorder known as tardive dyskinesia. They sued the generic manufacturers, alleging that those manufacturers knew tardive dyskinesia was a known side effect of long-term use of the drug, and should have used a different, stronger warning label than the one they did. The manufacturers argued that they could not be sued under state law because these state-law claims were incompatible with the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act, which required generic manufacturers to use (without varying) the same label the FDA had approved for branded versions of the drug.

The Fifth and Eighth Circuits rejected the manufacturers' position, finding the generic manufacturers could have taken steps to strengthen the warnings they distributed with their products. The *Mensing* Court agreed with the manufacturers that the Hatch-Waxman Amendments, as construed by the FDA, required generic manufacturers to use the same safety and efficacy labeling as their brand-name counterparts. The Court further agreed that those regulations did not permit generic drug manufacturers to strengthen or add warnings unilaterally, or to send "Dear Doctor" letters containing new warning information.

The *Mensing* Court held that plaintiffs' failure-to-warn claims were preempted because -- as the generic manufacturers had argued -- it was impossible for those manufacturers to comply with the FDA's labeling requirements, and also to adopt the stricter labeling that the plaintiffs sought under state law. The fact that the manufacturers could have approached the FDA and requested that the Government strengthen the label, even if true, was irrelevant: "When a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party can not independently satisfy those state duties for pre-emption purposes."<sup>3</sup>

<sup>1</sup> Earlier this year, before the U.S. Supreme Court ruling in *Pliva v. Mensing, Inc.* (see fn 2), Ironshore published an article entitled "Will Federal Preemption protect Generic Pharma from Plaintiff's State Law Failure to Warn Claim?" outlining the issues and arguments before the U.S. Supreme Court in *Mensing*. The article appears on the Ironshore website at [http://www.ironshore.com/pdf/Preemption-Protect\\_05.18.11.pdf](http://www.ironshore.com/pdf/Preemption-Protect_05.18.11.pdf). This is the second article in the IronHealth series discussing federal preemption and generic drug manufacturers. The assistance of Craig Stewart, Esq. and Eric Hermanson, Esq. of Edwards Angell Palmer & Dodge, in the preparation of these articles is gratefully acknowledged.

<sup>2</sup> 131 S. Ct. 2567 (June 23, 2011).

<sup>3</sup> Id. At 2581

## B. The Implications of Mensing on Generic Pharma and Brand Name Manufacturers

Generic drug manufacturer defendants reacted to Mensing with predictable euphoria. Defense lawyers described the decision as “a huge victory,”<sup>4</sup> which “effectively end[ed] the ability for users of a generic drug product to file a state-law suit premised on the generic manufacturer’s alleged failure to warn.”<sup>5</sup> Over the last several months, a number of generic manufacturers have filed motions to dismiss, in scores of metoclopramide cases around the country.

More recently, however, some of the euphoria appears to have receded, as plaintiffs have opposed defendants’ dismissal motions, and attempted to regroup. On July 18, 2011, the plaintiffs in Mensing filed a petition for Supreme Court rehearing, arguing that the Court “overlook[ed] the fact that the ... generic drug companies could have ‘independently’ complied with both state and federal law by simply suspending sales of general metoclopramide with warnings that they knew or should have known were inadequate.”<sup>6</sup> The petition was a long shot, and was denied.<sup>7</sup> Nonetheless, by characterizing the “suspension-of-sales” argument as one that the Supreme Court “overlooked,” the Mensing plaintiffs may be attempting to position themselves to advance this allegedly “overlooked” argument on remand in the lower courts.

Some other plaintiffs have focused on the section of the Mensing decision in which the Court assumed -- though it did not explicitly decide -- that generic manufacturers, while forbidden from making changes unilaterally to the labels of their products, nonetheless had a duty to propose additional warnings to the FDA when the manufacturers become aware of safety issues. This assumption was consistent with the FDA’s interpretation of its regulations, and with the Court’s general practice of deferring to an agency’s interpretation of its own regulations so long as that interpretation is “reasonable.” However, the Court’s assumption was contrary to the position taken by the generic manufacturers, who argued that there was no duty to request a strengthened label, and “no evidence of any generic drug manufacturer ever acting pursuant to such a duty.” Some plaintiffs’ counsel have argued that, by refusing to adopt the generic manufacturers’ position on this point, the Court may have left the door open for plaintiffs to assert other types of claims -- e.g., negligence -- against generic drug manufacturers who become aware of safety issues with their products but do not bring those issues to the attention of the FDA or the medical community. (However, plaintiffs may face a difficult path in bringing private claims for failure to meet that duty, in light of *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001), where the Supreme Court held that private state law claims alleging violations of FDA reporting requirements were pre-empted.)

Ultimately, the outcome of these various motions remains to be seen. Also, at issue is what effect the Mensing decision may have on other defendants, including brand-name manufacturers, who remain subject to state tort suits as a result of the different legal and regulatory regime. Will the plaintiffs, if denied recourse against the generic manufacturers, simply redouble their efforts to recover from these other defendants? Will plaintiffs seek to recover from the brand-name drug manufacturers under the so-called Conte theory, articulated and embraced by the California Supreme Court in *Conte v. Wyeth, Inc.*, 168 Cal.App.4th 89 (Cal. Ct. App. 2008). In *Conte*, the Court held that a brand-name prescription drug manufacturer may be found to owe a duty of care to patients who take a generic version of the drug in reliance on information that the brand-name has disseminated.

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4 See “Pliva v. Mensing: A Huge Victory For Manufacturers of Generic Drugs,” in DRI Today Case Reporter, <http://dritoday.org/commentary.aspx?ID=136>.

5 See K.Day, “Supreme Court Observations: Pliva v. Mensing,” in Washington Legal Foundation: The Legal Pulse, <http://wfllegalpulse.com/2011/07/12/supreme-court-observations-pliva-v-mensing/>.

6 See supra note 2.

7 *PLIVA, Inc. v. Mensing*, --- S.Ct. ---, 2011 WL 3557247, 80 USLW 3078 (U.S. Aug. 15, 2011).

Finally, it remains to be seen whether Congress or the FDA will move to enact legislation overruling *Mensing*. To some observers, Justice Thomas's decision in *Mensing* almost seemed to be inviting such legislation: From a plaintiff's perspective, as Justice Thomas himself conceded, a finding of preemption that applies only to generic manufacturers, but not name brand manufacturers, "makes little sense." However, as Justice Thomas wrote, "Congress and the FDA retain the authority to change the laws and regulations if they so desire."<sup>8</sup>

While there has been no effort yet to introduce such legislation, this may be an accident of timing, as much as anything else. *Mensing* was decided in June of this year when Congress was just entering what turned out to be a protracted legislative crisis over the federal debt ceiling. For most of the summer, the debt ceiling debate pushed most other legislative business to the side. But with those issues now temporarily resolved, some members of Congress may move to amend the Hatch-Waxman Amendments, as they did following the Supreme Court's preemption decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)<sup>9</sup>. It is also possible that the FDA may consider amending its regulations, to clarify or expand the duties of generic manufacturers in providing warnings to consumers.

### C. Conclusion

The *Mensing* decision creates new and powerful defenses for manufacturers of generic drugs in product liability cases. While generic manufacturers are justified in celebrating the decision, the plaintiffs' bar is not likely to surrender quietly, and defendants can expect that plaintiffs' counsel will continue to try to hold generic manufacturers liable in tort by whatever means remain available. Plaintiffs in a number of lower-court cases are raising new arguments and issues, in hopes of circumventing the *Mensing* proscription. Courts, addressing these arguments, are only just beginning to grapple with *Mensing*'s scope, implications, and reach.

As noted in our prior article on federal preemption, (available at: [http://www.ironshore.com/pdf/Preemption-Protect\\_05.18.11.pdf](http://www.ironshore.com/pdf/Preemption-Protect_05.18.11.pdf)) the state-law failure to warn theories that are at the heart of the *Mensing* are only one of several theories of liability that are generally pursued by plaintiffs against manufacturers or distributors. Other theories pursued by plaintiffs -- apart from the failure to warn under state law -- include strict liability, negligence, fraud, deceptive advertising, or even intentional or malicious conduct.

In the end, while the *Mensing* decision seems clearly to have tilted the playing field in the generic manufacturers' favor, the game (at least for now) is on going. As one of the major providers of liability insurance to the generic pharmaceutical industry, Ironshore is monitoring these developments closely.

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<sup>8</sup> Id. At 2582

<sup>9</sup> On March 5, 2009, both the House and the Senate proposed legislation which would have amended the Federal Food, Drug, and Cosmetic Act to reverse the 2008 Supreme Court decision in *Medtronic v. Riegel* H.R. 1346; S. 540. The law, if passed, would have permitted plaintiffs to bring state law liability suits against medical device companies with respect to devices approved by the federal Food and Drug Administration ("the FDA") under the premarket approval ("PMA") process, a longer, more complicated evaluation process undertaken by the FDA in approving a device. Although hearings were held on August 4, 2009 by the Senate Committee on Health, Education, Labor & Pensions, the bill was not reported out of committee.

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